# TENT COOPERATION TRE. /

	From the INTERNATIONAL BUREAU		
PCT	То:		
NOTIFICATION OF ELECTION	Assistant Commissioner for Patents United States Patent and Trademark		
(PCT Rule 61.2)	Office		
·	Box PCT Washington, D.C.20231		
	ÉTATS-UNIS D'AMÉRIQUE		
Date of mailing (day/month/year)			
15 February 2000 (15.02.00)	in its capacity as elected Office		
International application No.	Applicant's or agent's file reference		
PCT/CA99/00529	GP/10875.79		
International filing date (day/month/year)	Priority date (day/month/year)		
04 June 1999 (04.06.99)	04 June 1998 (04.06.98)		
Applicant			
SINDERBY, Christer et al			
	e <sub>e</sub> t.		
1. The designated Office is hereby notified of its election made	:		
X in the demand filed with the International Preliminary	Examining Authority on:		
30 December 1999 (30.12.99)			
	······································		
in a notice effecting later election filed with the Interna	ational Bureau on:		
2. The election X was			
was not			
	Discount of the state time time to and an		
made before the expiration of 19 months from the priority do Rule 32.2(b).	ate or, where Rule 32 applies, within the time limit under		
· ·			
,			

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

S. Mafla

Telephone No.: (41-22) 338.83.38

Telephone No.: (41-22) 3



RECO 0 8 SEP 2000

**PCT** 

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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's	or ag	ent's file reference	FOR EURTHER ACTION		cation of Transmittal of International
GP/1087	5.79		FOR FURTHER ACTION	R FURTHER ACTION Preliminary Examination Report (Form PCT/IPEA/416)	
Internation	al app	lication No.	International filing date (day/mor	te (day/month/year) Priority date (day/month/year)	
PCT/CA	99/00	0529	04/06/1999		04/06/1998
A61M16		ent Classification (IPC) or na	ational classification and IPC		
Applicant UNIVER	SITE	DE MONTREAL et al.			
		ational preliminary exam smitted to the applicant a		ed by this Int	ernational Preliminary Examining Authorit
2. This	REPO	ORT consists of a total of	4 sheets, including this cover	sheet.	
b	een a	amended and are the bas	d by ANNEXES, i.e. sheets of sis for this report and/or sheets 07 of the Administrative Instruc	containing r	on, claims and/or drawings which have ectifications made before this Authority he PCT).
Thes	e ann	exes consist of a total of	17 sheets.		
			•		
3. This i	report ⊠	contains indications rela	ating to the following items:		
		•			
Ш	$\boxtimes$	•	ppinion with regard to novelty, i	nventive step	and industrial applicability
IV		Lack of unity of invention	on		
V			nder Article 35(2) with regard to ons suporting such statement	o novelty, inv	rentive step or industrial applicability;
VI		Certain documents cite	ed		
VII		Certain defects in the in	• •		
VIII		Certain observations o	n the international application		
Date of sut	missi	on of the demand	Date of	of completion o	f this report
30/12/19	99				O 4. 09. QQ
	exam	g address of the international ining authority:	al Autho	rized officer	STATE SOUTH NO. 15. NO
<u>a)</u> )	D-8	opean Patent Office 0298 Munich	Valfo	ort, C	(the state of the
		+49 89 2399 - 0 Tx: 523656	o epina a		Sep. 13 DIM: 1371



International application No. PCT/CA99/00529

#### I. Basis of the report

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):
Description, pages:

	1-24	1	as originally filed	
	Cla	ims, No.:		
	1-59	Э	with telefax of	30/12/1999
	Dra	wings, sheets:		
	1/10	)-10/10	as originally filed	
2.	The	amendments have	e resulted in the cancellation of:	
		the description,	pages:	
		the claims,	Nos.:	
		the drawings,	sheets:	•
3.			een established as if (some of) the beyond the disclosure as filed (F	ne amendments had not been made, since they have been Rule 70.2(c)):
4.	Add	litional observation	s, if necessary:	
Ш.	Nor	n-establishment o	f opinion with regard to novel	ty, inventive step and industrial applicability
			e claimed invention appears to lable have not been examined in	be novel, to involve an inventive step (to be non-obvious), respect of:
		the entire internat	ional application.	·
	Ø	claims Nos. 1-59.		
be	caus	se:		



International application No. PCT/CA99/00529

	the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination ( <i>specify</i> ):
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
Ø	no international search report has been established for the said claims Nos. 1-59.

# INTERNATIONAL PRELIMINARY

International application No. PCT/CA99/00529

### **EXAMINATION REPORT - SEPARATE SHEET**

#### Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No international search report has been established for the amended claims 1 to 1. 59 filed on 30.12.1999, in replacement of unique originally filed claim 1, thus no meaningful examination can be carried out for those amended claims.



#### **CLAIMS**

1. A closed loop system for controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical lung ventilator, comprising:

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means for measuring (a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volume, (b) the inspiratory volume for a given EMG intensity, and/or (c) a combination of (a) and (b); and

means for controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical lung ventilator in response to measurement of (a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volume. (b) the inspiratory volume for a given EMG intensity, and/or (c) the combination of (a) and (b);

wherein the closed loop system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level.



From	lhe
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INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: Dubuc, J. **GOUDREAU GAGE DÜBUC &** MARTINEAU WALKER The Stock Exchange Tower 800 Place Victoria, Suite 3400

WRITTEN OPINION

Montréal, Québec H4Z 1E9 CANADA		(PCT Rule 66)		
		Date of mailing (day/month/year)	23.02.2000	
Applicant's or agent's file reference		REPLY DUE	within 3 month(s) from the above date of mailing	
GP/10875.79			ItoUt the above date of maining	
International application No PCT/CA99/00529	tnternational filing date (d	day/month/year)	Priority date (day/month/year) 04/06/1998	
International Patent Classification (IPC) or both	<u> </u>	dIPC		
A61M16/00				
Applicant				
UNIVERSITE DE MONTREAL et al.				

- This written opinion is the first drawn up by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - Basis of the opinion
  - ☐ Priority
  - Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Ш
  - Lack of unity of invention IV
  - Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain document cited VI.
  - Certain defects in the International application VII
  - Certain observations on the international application VIII
- The applicant is hereby invited to reply to this opinion.

See the time limit indicated above. The applicant may, before the expiration of that time limit. Whon?

request this Authority to grant an extension, see Rule 66.2(d).

By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. How?

For the form and the language of the amendments, see Rules 66.8 and 66.9.

For an additional opportunity to submit amendments, see Rule 66.4. Also:

For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.

For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 04/10/2000.

Name and mailing address of the international preliminary examining authority:



European Patent Office D-80298 Munich

Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Authorized officer / Examiner

Vallort, C

Formalities officer (Incl. extension of time limits)

Moris, A

Telephone No. +49 89 2399 8588







### WRITTEN OPINION

International application No. PCT/CA99/00529

ı.	Bas	is of	the	opi	inion
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1	. TI In	nis opinion has been response to an Invli	drawn on the basis of (substitu atlon under Article 14 are referre	e sheets which have been furnished to the receiving Office ad to in this opinion as "originally filed".):
	D	escription, pages:		
	1-	24	as originally filed	
	CI	aims, No.:		
	1-	59	with telefax of	30/12/1999
	Dr	awings, sheets:		
	1/1	0-10/10	as originally filed	
2.	Th	e amendments have	resulted in the cancellation of:	
		the description,	pages:	
		the claims,	Nos.:	
		the drawings,	sheets:	
3.	Thi con	s opinion has been e sidered to go beyon	established as if (some of) the aid the disclosure as filed (Rule 7	mendments had not been made, since they have been 0.2(c)):
4.	Add	litional observations	, if necessary:	
	888	separate sheet		
III.	Noi	n-establishment of	opinion with regard to novelty	, inventive step and industrial applicability
The or t	e qu lo be	estions whether the industrially applica	claimed invention appears to be ble have not been and will not b	novel, to involve an inventive step (to be non-obvious).
		the entire Internatio	nal application,	
	Ø	claims Nos. 1-59,		
bec	aus	e:		
		the said internationa not require an interr	al application, or the said claims national preliminary examination	Nos. relate to the following subject matter which does (specify):

ь



514-397-4

#### WRITTEN OPINION

International application No. PCT/CA99/00529

	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
×	no international search report has been established for the said claims Nos. 1-59

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet





# WRITTEN OPINION SEPARATE SHEET

International application No. PCT/CA99/00529

# Re Item I Basis of the opinion

(additional observations)

- 1. The examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT has not been carried out yet.
- 2. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

### Re Item VII

## Certain defects in the international application

- The independent claim should be cast in the two part form according to Rule 6.3.b)
   PCT.
- All the claims should contain reference numerals according to Rule 6.2.b) PCT.

The demand must be filed directly to competent International Preliminary Examining ority or, if two or more Authorities are with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line.

## PCT

CHAPTER II

#### **DEMAND**

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only				
Identification of IPBA		Date of receipt of D	EMAND	
Box No. 1 IDENTIFICATION OF THE INTERNATIONAL APPLICATION		APPLICATION	Applicant's or agent's file reference GP/10875.79	
International application No. PCT/CA99/00529	International filing date 04 June 1999	(day/month/year) ( 04/06/99 )	(Earliest) Priority date (day/month/year) 04 June 1998 ( 04/06/98 )	
Title of invention PROPORTIONAL PRESSURE ASSIST	T VENTILATION CON	TROLLED BY A DIA	PHRAGM ELECTROMYOGRAPHIC	
Bur No. 11 APPLICANT(S)				
Name and address: (Family name followed designation. The address	by given name: for a le	gal entity, full official	Telephone No.:	
_	s mušt include postal code i	and name of country.)	(514) 343-2307	
UNIVERSITÉ DE MONTRÉAL 2900 Boulevard Édouard-Montpetit			Facsimile No.:	
Montréal, Québec			(514) 343-2326	
Canada, H3C 3J7			Teleprinter No.:	
State (that is, country) of nationality:  CA		State (that is, country,	) of residence: CA	
Name and address: (Family name followed l	by given name; for a legal	entity, full official design	nation. The address must include postal code and	
SINDERBY, Christer				
12750, 27th Avenue				
Montreal, Quebec Canada, H1E 129				
Canada, TTE 123			•	
State (that is, country) of nationality:		State (that is, country	) of residence:	
CA ,	•	CA		
Name and address: (Fumily name followed in name of country.)	by given name; for a legal	entity, full official design	nation. The address must include postal code and	
BECK, Jennifer				
12750, 27th Avenue				
Montreal, Quebec Canada, H1E 1Z9				
Callada, FIE 125	•			
·				
State (that is, country) of nationality:	<del></del>	State (that is, country	) of residence:	
CA			CA	
Further applicants are indicated on a	a continuation sheet.			



Sheet No. . ?.

International	application No.	
PC	T/CA99/00529	ì

BOX NO. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE			
The following person is agent common representative			
and has been appointed earlier and represents the applicant(s) also for international	al preliminary examination.		
is hereby appointed and any curlier appointment of (an) agent(s) /common re	presentative is hereby revoked.		
is hereby appointed, specifically for the procedure before the International Praddition to the agent(s)/common representative appointed earlier.	eliminary Examining Authority, in		
Name and address: (Family name followed by given name; for a legal entity, full official	Telephone No.:		
The address must include postal code and name of country.) DUBUC, Jean H.; LECLERC, Alain M.; PRINCE, Gaétan; LUPIEN, Marc	(514) 397-7609		
GOUDREAU GAGE DUBUC & MARTINEAU WALKER	Facsimile No.:		
The Stock Exchange Tower 800 Place Victoria, Sulte 3400	(514) 397-4382		
Montreal, Quebec, H4Z 1E9, CANADA	Teleprinter No.:		
Address for correspondence: Mark this check-box where no agent or common the space above is used instead to indicate a special address to which correspond	representative is/has been appointed and idence should be sent.		
BOX NO. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION	,,,		
Statement concerning amendments:*			
1. The applicant wishes the international preliminary examination to start on the basis o	f:		
the international application as originally filed.			
the description as originally filed			
as amended under Article 34			
the claims as originally filed			
as amended under Article 19 (together with any accompa	nying statemen!)		
the drawings as originally filed			
as amended under Article 34			
<ol> <li>The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.</li> <li>The applicant wishes the start of the international preliminary examination to be postponed until the expiration of</li> </ol>			
20 months from the priority date unless the International Preliminary Examination			
amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments			
(Rule 69.1(d)). (This check-box may be marked only where the time limit und * Where no check-box is marked, international preliminary examination will start on t			
originally filed or, where a copy of amendments to the claims under Article 19			
application under Article 34 are received by the International Preliminary Examining a written opinion or the international preliminary examination report, as so amended			
Language for the purposes of international preliminary examination: ENGLISH			
which is the language in which the international application was filed.			
which is the language of a translation furnished for the purposes of internation	nal search.		
which is the language of publication of the international application.			
which is the language of the translation (to be) furnished for the purposes of i	nternational preliminary examination.		
Box No. V ELECTION OF STATES	I and the Charles Harden		
The applicant hereby elects all eligible States (that is, all States which have been designated PCT)	i ana wnich are nouna by Chapier II of the		
excluding the following States which the applicant wishes not to elect:	·		



- 4	
•	In

			•			International appl	ication No.
		Sheet No.	. ়			PCT/C/	199/00529
Box	No. VI CHECK LIST						
The	e demand is accompanied by the following of x No. IV, for the purposes of international pro	elements, in the lectiminary examin	angu alion	age re	eferred to in		ional Preliminary Authority use only not received
1.	translation of international application	:			shcets		
2.	amendments under Article 34	:			19 sheets		
3.	copy (or where required, translation) of amendments under Article 19	<b>:</b> .			sheets		
4.	copy (or, where required, translation) of statement under Article 19	:			sheets		
5.	lener	:			1 sheets		
6.	other (specify)	:			sheets		
The	demand is also accompanied by the item(s) n	narked below:				······································	
1.	fee calculation sheet		4.		statement ex	plaining lack of sign	ature
2.	separate signed power of attorney		5.		nucleotide a	nd or amino acid sequadable form	uence listing in
3.	copy of general power of attorney; reference number, if any:		6.		other (specif		
Box	No. VII SIGNATURE OF APPLICA	NT, AGENT (	or c	СОМ	MON REP	RESENTATIVE	
Nex	I to each signature, indicate the name of thious from reading the demand).	e person signing	and	the c	apacity in wh	ich the person signs	(if such capacity is not
	GOUDREA	AU GAGE DUBI	7C 8	MAF	RTINEAU W	ALKER	
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	· BY: (0.						
	GAÉTAN	PRINCE					
	O/L ////	, , , , , , ,					
	For Internal	tional Preliminary	Exa	minir	ng Authority (	ise only	
1.	Date of actual receipt of DEMAND:						
2.	Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):						
3.	The date of receipt of the demand is from the priority date and item 4 or	AFTER the expired, below, does no	ailoi t app	of 19 ly.	9 months	The applic informed	eant has been accordingly.
4.	The date of receipt of the demand is Rule 80.5.	WITHIN the per	iod o	f 19 n	nonths from t	he priority date as ext	ended by virtue of
5.	5. Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.						
_		- For Internation	nal B	lureau	use only —		
De	mand received from IPEA on:						





**CHAPTER II** 

# **PCT**

### FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

		For International Preliminary Examining Authority use only
International application No.	PCT/CA98/00529	
Applicant's or agent's file reference	GP/10875.79	Date stamp of the IPEA
Applicant UNIVERSITÉ DE MONTRÉAI	_ et al	
Calculation of prescribed fee	<b>.</b>	
1. Preliminary examination fed		2,998.29 P
2. Handling fee (Applicants entitled to a reduction of a Where the applicant is (a entitled, the amount to be e handling fee.)	ntered at H is 23% of the	289.46 H
3. Total of prescribed fees Add the amounts entered at and onter total in the TOTA	P and H L box	3,287.75 TOTAL
Mode of Payment		
authorization to charge account with the IPEA	deposit (see below) cash	
cheque postal money order	revenue	e stamps s
≥ bank draft	other (s	specify):
	•	,
Deposit Account Authorizati The IPEA/	this check-hor may be marked	of be available at all IPEAs)  ne total fees indicated above to my deposit account.  only if the conditions for deposit accounts of the IPEA so permit) is my deficiency or credit any overpayment in the total fees indicated
Deposit Account Number	Date (day/month/year)	Signature (I. V. v. v. t. Goodsulution (I.

Form PCT/IPEA/401 (Annex) (July 1998)

LegalStar 1998, Form PCTDFEE

See Notes to the fee calculation sheet



### REQUEST

iving Office use only
International Application No.
International Filing Date
Name of receiving Office and "PCT International Application"

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.	Name of receiving Office and "PCT International Application"
	Applicant's or agent's file reference (if desired) (12 characters maximum)  GP/10875.79
Box No. I TITLE OF INVENTION AUTOMATIC ADJUSTMENT OF APPLIED LEVELS OF VE CLOSED-LOOP CONTROL OF NEURO-VENTILATORY EF Box No. II APPLICANT	NTILATORY SUPPORT AND EXTRINSIC PEEP BY
Name and address: (Family name followed by given name; for a The address must include postal code and name of country. The country Bax is the applicant's State (that is, country) of residence if no State of resuntive Country Description of the Country Description	of the address indicated in this   This person is also inventor
State (that is, country) of nationality: CA	State (that is, country) of residence:
This person is applicant all designated all designated for the purposes of: States all designated the United St	d States except the United States the States indicated in the Supplemental Box
Box No. III FURTHER APPLICANT(S) AND/OR (FURT	HER) INVENTOR(S)
Name and address: (Family name followed by given name: for a legal en The address must include postal cade and name of country. The country Bax is the applicant's State (that is, country) of residence if no State of res. SINDERBY, Christof 12750, 27th Avenue Montreal, Quebec Canada H1E 129	of the address indicated in this idence is indicated below.)  This person is:  applicant only  supplicant and inventor  inventor only (If this check-box is marked, do not fill in below.)
State (that is, country) of nationality: CA	State (that is, country) of residence:  CA
This person is applicant all designated all designated for the purposes of:  all designated the United States  Further applicants and/or (further) inventors are indicated on	a continuation sheet.
Box No. IV AGENT OR COMMON REPRESENTATIVE	OR ADDRESS FOR CORRESPONDENCE
The person identified below is hereby/has been appointed to act or of the applicant(s) before the competent International Authorities a	
Name and address: (Family name followed by given name; for designation. The address must include postal of DUBUC, Jean H.; LECLERC, Alain M.; PRINCE, Gaétan; LL GOUDREAU GAGE DUBUC & MARTINEAU WALKER The Stock Exchange Tower	ode and name of country.) (514) 397-7609
800 Place Victoria, Sulte 3400 Montreal, Quebec, H4Z 1E9, CANADA	Teleprinter No.
Address for correspondence: Mark this check-box where n space above is used instead to indicate a special address to w	to agent or common representative is has been appointed and the which correspondence should be sent.

Form PCT/RO/101 (first sheet) (July 1998)

LogalStar 1998, Form PCTREQ

See Notes to the request form

2-00	10:24	De-GOU	DREAU GAO	E DUBUC				+1-514-397-4	382	E-672	P.06	Trav161
						Sheet	No <del>?</del> ,					
Cont	tinuatio	n of Box	No. III	FURTH	ER APP			R (FURTHE	R) INV	ENTOR(S		
								eet is not to b				
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1275	K, Jennif 0, 27th A real, Qui	lvenue								applicant	•	
Cana H1E											nly <i>(If th</i>	is chook-ba ill in below.)
State CA	(that is, c	ouniry) o	fnationali	ty:			State (th	al is. country)	of reside	nce:	<del> </del>	
	erson is a		all o	designated	all the	designated United St	States exercises of Am	ept K the	United S America	States	the States the Suppl	indicated in emental Bo
The add	dress musi	include p	ostal code i	and nume of	country. 1	The country	of the addre	oial designation. ss indicated in th licated below.)		s person is:	-	
					-	-				applicant	only	
										applicant t	and inven	tor
					٠							ls check-bax ll in below.)
State	(ihai is. o	ountry) o	f nationali	ity:			State (th	at is, country) (	of resider	ice:		
	erson is a purposes		all c	lesignated es	all the	designated United St	States exc ates of Am	ent the	United S America		he States he Suppl	indicated in emental Box
The ada	tress must	include p	osial code d	and name of	country. 7	he country	of the addre	ial designation. is indicated in th icated below.)	This	person is:		
										applicant o	only	
										applicant a	nd invent	or
			*									e oheck-bax Il in below.)
State (	that is, c	ομπιτγ) ο	f nationali	ty:	,		State (th	at is, country) (	of resider	ice:		
	erson is a purposes		all d	esignated	all the	designated United Sta	States excentes of Amo		United S Imerica o	tates U	he States he Supple	indicated in emental Box
he ada	iress musi	include p	ostal code a	ind name of	country. T.	he country	of the addres	rial designation. is indicated in the icated below.)	is This	person is:		
			•		-					applicant o	•	
									1 1 1	applicant a	ua invent	or

Further applicants and/or (further) inventors are indicated on another continuation sheet. Form PCT/RO/101 (continuation sheet) (July 1998)

all designated States

State (that is, country) of nationality:

This person is applicant for the purposes of:

Legalisar 1998, Form PCTREQ

the United States of America only

State (that is, country) of residence:

all designated States except the United States of America

See Notes to the request form

the States indicated in the Supplemental Box

inventor only (If this check-bax is marked, do not fill in below.)

04-14-00

			-67		
Box !	NaV	DESIGNATION		35.3	
			(a) (m	ark the	applicable check-passes: at least one must be marked):
_		Patent	1 6		the MOVIMalauri CD Sudan C7 Supplied 1/City
B		ZW Zimbabwe, and any other State which is a Cor	ntracti	ng Sta	tho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, see of the Harare Protocol and of the PCT
	EA	Moldova, RU Russian Federation, TJ Tajikistan, of the Eurasian Patent Convention and of the PCT	TM T	urkme	rus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of mistan, and any other State which is a Contracting State
X	EP	DK Denmark ES Socia El Finland FR France Gl	B Unit	ed Kir	vitzerland and Liechtenstein, CY Cyprus, DE Germany, 18dom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, 19 other State which is a Contracting State of the European
×	OA	OAPI Patent: BF Burking Faso, BJ Benin, CF Ce	fali, M nd a Co	IR Ma ontrac	n Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, uritania. NE Niger, SN Senegal, TD Chad, TG Togo, and ting State of the PCT (if other kind of protection or treatment
Mario	nai Pa	nent (if other kind of protection or treatment desired spec	ify on a	dotted.	line):
<b>83</b>	AI	Albania	<b>2</b> 29		Lesotho
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80	BB	Bachados	52	MA	
<b>23</b>	BG	Bulgaria			
83	BR	Brazil	<b>20</b>		Mongolia
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83		Canada	<b>2</b>	MX	Mexico
Ø		and LI Switzerland and Liechtenstein			Norway
29	CN	China	23	NZ	New Zealand
	CU	Cuba	四	PL	Poland
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		Germany	X	RO	Romania
83		Denmark	23	RU	Russian Federation
83		Estonia	$\widetilde{\mathbf{z}}$	SD	Sudan
8	ES	Spain	2	SE	Sweden
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83		Grenada Georgia	(Z	SL	Sierra Leone
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3		Gambia	[3]	TM	Turkmenistan
83		Crostis	<b>123</b>	TR	Turkey
	HU	Hungary			Trinidad and Tobago
$\mathbf{\omega}$	ID	Indonesia	[23]		Ukraine
	IL	Israel	2	UG	Uganda
<b>6</b> 3	IN	India	四	US	United States of America
	IS	Iceland			
	115	Japan	(H	UZ	Uzbekistan
<u>63</u>	KE	Kenya		VN	Viet Nam
<b>20</b>	KG	Kyrgyzstan	[2]	YU	Yugoslavia
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Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the purment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit i

Sec V Sect Burgary

04-12-00 10:25 De-GOUDREAU GAGE DUBUC +1-514-397-4382 E-672 P.08 Trav161 Sheet No. . . 4. . . . Box No. VI PRIORITY further priority claims are indicated in the Supplemental Box. Filing date Number Where earlier application is: of earlier application of earlier application national application: regional application:\* international application: (day/month/year) country regional Office receiving Office item (1) 4 June 1998 2,239,673 CA itcm (2) item (3) The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s):

\* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Bas at least one country party to the Ports Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 1.10(b)(ii)). See Supplemental Bas. Box No. VII INTERNATIONAL SEARCHING AUTHORITY Choice of International Searching Authority (ISA) Request to use results of earlier search; reference to that search (If un earlier (If two or more International Searching Authorities are competent to carry out the international search, indicate the search has been carried out by or requested from the International Searching Authority): Authority chosen: the two-letter code may be used): Date (day/month/year) Country (or regional Office) ISA/ Box No. VIII CHECK LIST: LANGUAGE OF FILING This international application contains This international application is accompanied by the item(s) marked below: the following number of sheets: 1. X fee calculation sheet request 2. A separate signed power of attorney description (excluding) 3. a copy of general power of attorney; reference number, if any: sequence listing part) 24 4. A statement explaining lack of signature claims 5. priority document(s) identified in Box No. VI as items(s): abstract 6. Translation of international application into (language): drawings 10 7. 

— separate indications concerning deposited microorganism or other biological material sequence listing part 8. In nucleotide and/or amino acid sequence listing in computer readable form of description 9. ather (specify): Total number of sheets ; 40 Figure of the drawings which Language of filing of the international application: should accompany the abstract: 10 **ENGLISH** Box No. LX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not abvious from reading the request). GOUDREAU GAGE DUBUC & MARTINEAU WALKER **GAÉTAN PRINCE** For receiving Office use only

1.	Date of actual receipt of the purported international application:	erving Office use only	2. Drawings:
3.	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		received:
4.	Date of timely receipt of the required corrections under PCT Article 11(2):		not received:
5.	International Searching Authority (if two or more are competent): ISA/	6. Transmittal of search copy delayed until search fee is paid	

	For International Bureau use only	<del></del>
Date of receipt of the record copy by the International Bureau:	•	

This sheet is part of and does not count as a sheet of the Internation plication.

FEE CALCULAT		Por receiving Office	use only
Annex to the	Request	International application No.	
Applicant's or agent's file reference	GP/10875.79	Date stamp of the receiving Office	
Applicant UNIVERSITÉ DE MONTRÉAL			
2. SEARCH FEE International search to be carried of (If two or more International Sapplication, indicate the name of the International Application contains a specific street international application contains and a specific street international application and busing sheets  The international application contains and busing sheets  The international application contains and busing sheets  The international application contains and specific street sheet	and by  Authorities are compete the Authority which is chasen to car  ains 40 sheets.  Description = 100000000000000000000000000000000000	200.00 T	
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The designation fees are not pai	d at this time.		
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is hereby deposit ac	authorized to charge any deficiency count.	or credit any overpayment in the total fer	
27G07	June 4, 1999		
Deposit Account Number	Date (day/month/year)	Signature See OSTREES See Note	

## PATENT COOPERATION TRF

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Dubuc, J. **GOUDREAU GAGE DUBUC &** MARTINEAU WALKER The Stock Exchange Tower 800 Place Victoria, Suite 3400 Montréal, Québec H4Z 1E9 CANADA

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY **EXAMINATION REPORT** (PCT Rule 71.1)

Date of mailing (day/month/year)

0 4, 09, 00

Applicant's or agent's file reference GP/10875.79

International application No.

PCT/CA99/00529

International filing date (day/month/year)

04/06/1999

Priority date (day/month/year) 04/06/1998

IMPORTANT NOTIFICATION

Applicant

UNIVERSITE DE MONTREAL et al.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and fumish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

1 / SEE 2000

Name and mailing address of the IPEA/

European Patont Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465

Authorized officer

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Wilde Dogen Bade this in La Ginag. D.P. 243 PLAGE VICTORIA GONTHEAL OURRED HAZ NO.

357. YEDE

Tel +49 89 2399-7447





# **PCT**

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GP/10875.79			FOR FURTHER AC	CTION		ation of Transmittal of Internatio Examination Roport (Form PC		
Internation	al app	lication No.	International filing date (	day/month	yoar)	Priority date (day/month/year,	)	
PCT/CA99/00529 04/06/1999			04/06/1999			04/06/1998		
	nternational Patent Classification (IPC) or national classification and IPC A61M16/00							
Applicant UNIVER	SITE	DE MONTREAL et al.					,	
	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.							
2. This	REPO	ORT consists of a total of	4 sheets, including this	s cover sh	eet.			
ь	een a		ls for this report and/or	sheets co	ntaining re	n, claims and/or drawings w clifications made before this e PCT).		
Thesi	ann	exes consist of a total of	17 sheels.					
3. This r	eport	contains indications relat	ing to the following iten	ns:		·		
1	凶	Basis of the report						
11	Ü	Priority					•	
111	$\boxtimes$	Non-establishment of op-	pinion with regard to no	velty, inve	entive step (	and industrial applicability		
IV		Lack of unity of inventio	n					
V		Reasoned statement un citations and explanatio			ovelty, inve	ntive step or industrial appli	cability;	
VI		Certain documents cite	d ·					
VII		Certain defects in the in	ternational application					
VIII	VIII   Certain observations on the international application  .							
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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00529

I. Basis	of t	he r	eport
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<ol> <li>This report has been drawn on the basis of (substitute sheets which have been furnished to the response to an invitation under Article 14 are referred to in this report as "originally filed" and are the report since they do not contain amendments.):</li> </ol>			on under Article 14 are referred to in this report as "originally filed" and are not annexed to		
	Des	scription, pages:			
	1-24 Claims, No.:		as originally filed		
	1-5	9	with telefax of 30/12/1999		
Drawings, sheets:					
	1/1	0-10/10	as originally filed		
2.	The amendments have resulted in the cancellation of:				
		the description,	pages:		
		the claims, the drawings.	Nos.: sheets:		
3.	This report has been established as it (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):				
4.	Additional observations, if necessary:				
<u> </u>	Noi	n-establishment of	opinion with regard to novelty, inventive step and industrial applicability		
The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:					
	☐ the entire international application.				
	Ø	claims Nos. 1-59.			

because:





# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00529

	the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination ( <i>specify</i> ):
	the description, claims or drawings (Indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
$\boxtimes$	no international search report has been established for the said claims Nos. 1-59.





# INTERNATIONAL PRELIMINARY International application No. PCT/CA99/00529 EXAMINATION REPORT - SEPARATE SHEET

#### Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. No international search report has been established for the amended claims 1 to 59 filed on 30.12.1999, in replacement of unique originally filed claim 1, thus no meaningful examination can be carried out for those amended claims.

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#### CLAIMS

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- 1) A method for substantially removing a common noise signal portion .from electrical signals produced by an electrical signal source having a polarity reversal region with a centre, said electrical signals having inverse polarities on opposite sides of the centre, said method comprising:
  - a) sensing a first electrical signal of a first polarity through first electrodes located on one side of the centre;
  - b) sensing a second electrical signal of a second polarity through second electrodes located on the other side of said centre;
  - c) sensing a third electrical signal through third electrodes located between said first electrodes and said second electrodes;
  - d) combining the first and second electrical signals into a combination signal; and
- e) combining the combination signal and the third electrical signal into an output signal.
- 2) A method for substantially removing a common noise signal portion as recited in claim 1, wherein:
  - said first and second polarities are opposite polarities;
    - combining the first and second electrical signals comprises subtracting one of the first and second electrical signals from the other of said first and second electrical signals to produce a combination signal substantially free from said common noise signal portion; and
    - combining the combination signal with the third electrical signal comprises adding the combination signal and the third electrical

CA 009900529



26

signal to produce said output signal still substantially free from said common noise signal portion and thereby substantially prevent output signal loss.

- 3) A method for substantially removing a common noise signal portion as recited in claim 1 or 2, further comprising differentially amplifying said first electrical signal, differentially amplifying said second electrical signal, and differentially amplifying said third electrical signal.
- 4) A method for substantially removing a common noise signal portion as recited in claim 1, 2 or 3, wherein sensing of said first, second and third electrical signals comprises forming with said first, second and third electrodes a series of electrodes having an axis extending through the centre of the polarity reversal region substantially in the direction of polarity reversal.

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5) A method for substantially removing a common noise signal portion as recited in claim 1, 2, 3 or 4, further comprising applying said output signal substantially free from said common noise signal portion to a ventilatory assistance system.

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6) A method for substantially removing a common noise signal portion as recited In claim 1, 2, 3, 4 or 5, wherein sensing of said first, second and third electrical signals comprises sensing first, second and third electromyographic signals, respectively, from at least one muscle of a patient, said at least one muscle constituting the electrical signal source.

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CA 009900529



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- 7) A device for substantially removing a common noise signal portion from electrical signals produced by an electrical signal source having a polarity reversal region with a centre, said electrical signals having inverse polarities on opposite sides of the centre, said device comprising:
  - a) a first input responsive to a first electrical signal having a first polarity sensed through first electrodes located on one side of the centre;
  - a second input responsive to a second electrical signal having a second polarity sensed through second electrodes located on the other side of said centre;
- c) a third input responsive to a third electrical signal sensed through third electrodes located between the first electrodes and the second electrodes;
  - d) means for combining the first and second electrical signals into a combination signal; and
- e) means for combining the combination signal and the third electrical signal into an output signal.
  - 8) A device for substantially removing a common noise signal portion as recited in claim 7, wherein:
    - said first and second polarities are opposite polarities;
    - the first and second electrical signals combining means comprises means for subtracting one of the first and second electrical signals from the other of said first and second electrical signals to produce a combination signal substantially free from said common noise signal portion; and
    - the means for combining the combination signal with the third electrical signal comprises means for adding the combination

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04-01-2000 CA 009900529



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signal and the third electrical signal to produce said output signal still substantially free from said common noise signal portion and thereby substantially prevent output signal loss.

- 9) A device for substantially removing a common noise signal portion as recited in claim 7 or 8, further comprising a first differential amplifier for amplifying said first electrical signal, a second differential amplifier for amplifying said second electrical signal, and third differential amplifier for amplifying said third electrical signal.
- 10 10) A device for substantially removing a common noise signal portion as recited in claim 7 or 8, wherein said first, second and third electrodes form a series of electrodes having an axis extending through the center of the polarity reversal region substantially in the direction of polarity reversal.
  - 11) A device for substantially removing a common noise signal portion as recited in claim 7, 8 or 9, further comprising a ventilatory assistance system to which is supplied said output signal substantially free from said common noise signal portion.
  - 12) A device for substantially removing a common noise signal portion as recited in claim 7, 8, 9, 10 or 11, further comprising means for extracting from sald first, second and third electrical signals, a first, second and third electromyographic signals from at least one muscle of a patient, said at least one muscle constituting said electrical signal source.

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- 13) A neuro-ventilatory efficiency computation method for monitoring/controlling the level of ventilatory assist produced by a ventilatory assistance system, comprising:
  - a) receiving a first signal representative of inspiratory effort and having a first amplitude;
- b) receiving a second signal representative of a lung volume and having a second amplitude;
  - c) calculating a relation between said first and second amplitudes at predetermined intervals; and
  - d) increasing or decreasing the ventilatory assist level depending on whether a present calculated value of said relation is higher or lower than a past calculated value of said relation by an amount exceeding a given threshold.
- 14) A neuro-ventilatory efficiency computation method as in claim 13,
   15 wherein said relation calculating comprises calculating a ratio between said first and second amplitudes at predetermined time intervals.
  - 15) A neuro-ventilatory efficiency computation method as in claim 13, wherein said relation calculating comprises calculating a ratio between said first and second amplitudes at intervals when one of said first and second amplitudes reaches a predetermined level.
- 16) A neuro-ventilatory efficiency computation method as in claim 13,
   14 or 15, wherein the ventilatory assist level increasing or decreasing
   comprises increasing the ventilatory assist level when said present calculated value of said relation is higher than said past calculated value of said relation by an amount exceeding the given threshold, and

CA 009900529



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decreasing the ventilatory assist level when said present calculated value of said relation is lower than said past calculated value of said relation by an amount exceeding said given threshold.

- 17) A neuro-ventilatory efficiency computation method as in claim 13,
   14, 15 or 16, wherein receiving the second signal representative of a lung volume comprises receiving a signal representative of a given lung volume.
- 18) A neuro-ventilatory efficiency computation method as in claim 13,
   10 14, 15, 16 or 17, wherein receiving the first signal representative of inspiratory effort comprises receiving a signal representative of a given level of inspiratory effort.
- 19) A neuro-ventilatory efficiency computation method as in claim 13,
   14, 15, 16, 17 or 18, further comprising generating an alarm signal when said present calculated value of said relation is higher or lower than the past calculated value of said relation by an amount exceeding said given threshold.
- 20 20) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, or 19, comprising manually performing said increasing or decreasing of the ventilatory assist level.
- 21) A neuro-ventilatory efficiency computation method as in claim 13,
   14, 15, 16, 17, 18, 19 or 20, comprising expressing the first signal representative of inspiratory effort as one of the following values: a mean

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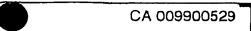
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of said first amplitude, a median of said first amplitude, and a peak of said first amplitude.

- 22) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19 or 20, comprising expressing the second signal representative of a lung volume as one of the following values: a mean of said second amplitude, a median of said second amplitude.
- 23) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22 wherein receiving the first signal representative: of inspiratory effort comprises receiving an electromyographic signal from at least one muscle of a patient.
- 24) A neuro-ventilatory efficiency computation device for
   15 monitoring/controlling the level of ventilatory assist produced by a ventilatory assistance system, comprising:
  - a) a first input for receiving a first signal representative of inspiratory effort and having a first amplitude;
  - b) a second input for receiving a second signal representative of a lung volume and having a second amplitude;
  - c) means for calculating a relation between said first and second amplitudes at predetermined intervals; and
  - d) means for increasing or decreasing the ventilatory assist level depending on whether a present calculated value of said relation is higher or lower than a past calculated value of said relation by an amount exceeding a given threshold.

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25) A neuro-ventilatory efficiency computation device as in claim 24, wherein:

the calculating means comprises a divider responsive to the first and second amplitudes for calculating a ratio between said first and second amplitudes at predetermined intervals;

the increasing or decreasing means comprises:

- a comparator responsive to the present calculated value and the past calculated value of said relation for producing a signal representative of a comparison between a present calculated value of said relation and a past calculated value of said relation; an adder interposed between the comparator and the ventilatory assistance system for adding a preset increment to or subtracting a preset decrement from said ventilatory assist level when the comparison signal exceeds a given threshold.
- 15 26) A neuro-ventilatory efficiency computation device as in claim 24 or 25, wherein said calculating means comprises means for calculating said relation at predetermined time intervals.
- A neuro-ventilatory efficiency computation device as in claim 24,
   or 25, wherein said calculating means comprises means for calculating said relation at intervals when one of said first and second amplitudes reach a predetermined level.
- 28) A neuro-ventilatory efficiency computation device as in any one of claims 25 to 27, wherein said adder comprises means for adding said preset increment to said ventilatory assist level when said present calculated value of said relation is higher than said past calculated value

CA 009900529



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of said relation by an amount exceeding said given threshold, and means for subtracting said preset decrement from said ventilatory assist level when said present calculated value of said relation is lower than said past calculated value of said relation by an amount exceeding said given threshold.

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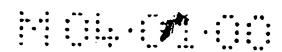
- 29) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 28, wherein the second signal representative of a lung volume is a signal representative of a given lung volume.
- 30) A neuro-ventilatory efficiency computation device as In any one of claims 24 to 28, wherein the second signal representative of inspiratory effort is a signal representative of a given level of inspiratory effort.
- 31) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 30, further comprising an alarm generator to produce an alarm signal when said present calculated value of said relation is higher or lower than the past calculated value of said relation by an amount exceeding said given threshold.
- 32) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 31, wherein said adder comprises a manual adjustment system to add said preset increment to or subtracting said preset decrement from said ventilatory assist levél.
- 25 33) A neuro-ventilatory efficiency computation device as in any one of claims 22 to 32, comprising means for expressing the first signal representative of inspiratory effort by means of one of the following

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CA 009900529



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values: a mean of said first amplitude, a median of said first amplitude, and a peak of said first amplitude.

- 34) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 32, further comprising means for expressing the second signal representative of a lung volume by means of one of the following values: a mean of said second amplitude, a median of said second amplitude, and a peak of said second amplitude.
- 35) A neuro-ventilatory efficiency computation device as in any one of
   claims 24 to 34, wherein the first signal representative of inspiratory effort
   is an electromyographic signal from at least one muscle of a patient.
  - 36) A method for monitoring/adjusting the level of positive end expiratory pressure produced by a pressure assist device in relation to a signal representative of inspiratory effort in view of minimizing the level of pre-inspiratory effort, comprising:
    - a) receiving a signal representative of inspiratory flow;
    - b) calculating from said inspiratory flow signal an onset time for inspiration;
- c) receiving a signal representative of inspiratory effort having an amplitude;
  - d) calculating a signal representative of pre-inspiratory effort in response to said onset time and said signal representative of inspiratory effort; and
- e) increasing or decreasing the level of positive end expiratory pressure in relation to said signal representative of pre-inspiratory effort.

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- 37) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 36, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on whether the amplitude of said signal representative of pre-Inspiratory effort is higher or lower than a given threshold.
- 38) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 37, wherein increasing of decreasing the level of positive end expiratory pressure comprises increasing the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is higher than said given threshold, and decreasing the level of positive end expiratory pressure when eaid signal representative of pre-inspiratory effort is lower than said given threshold.
- 39) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 38, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing one of the following parameters produced by said pressure assist device: a level of air flow, and a level of air volume.
- 40) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein calculating said signal representative of pre-inspiratory effort comprises

CA 009900529

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calculating said signal representative of pre-inspiratory effort at said onset time.

- 41) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein calculating said signal representative of pre-inspiratory effort comprises calculating said signal representative of pre-inspiratory effort during a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time.
- 10 42) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein:
  - a) calculating said signal representative of pre-inspiratory effort comprises calculating a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time; and
  - b) increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on whether said period is higher or lower than a given limit.

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43) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 39, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on both whether said period is higher or lower than the given limit, and whether the amplitude of the signal representative of pre-inspiratory effort is higher or lower than a given threshold.

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44) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 43, further comprising generating an alarm signal when said signal representative of pre-inspiratory effort is higher or lower than a given threshold.

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45) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 44, comprising manually performing the increase or decrease of the level of positive end expiratory pressure.

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46) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 45, comprising expressing said signal representative of inspiratory effort as one of the following values: a mean amplitude, a median amplitude, and a peak amplitude.

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47) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 46, wherein receiving said signal representative of inspiratory effort comprises receiving an electromyographic signal from at least one muscle of a patient.

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48) A controller for monitoring/adjusting the level of positive end expiratory pressure produced by a pressure assist device in relation to a signal representative of inspiratory effort in view of minimizing the level of pre-inspiratory effort, comprising:

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- a) a first input for receiving a signal representative of inspiratory flow having an onset time for inspiration;
- b) a second input for receiving a signal representative of inspiratory effort having an amplitude;
- c) a computer device responsive to said onset time and said signal representative of inspiratory effort to compute said signal representative of pre-inspiratory effort; and
- d) an adder/substractor for adding a preset increment to or subtracting a preset decrement from the level of positive end expiratory pressure in relation to said signal representative of pre-inspiratory effort.
- 49) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 48, wherein the adder/subtractor comprises means for adding the preset increment to or for subtracting the preset decrement from the level of positive end expiratory pressure depending on whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold.
- 20 expiratory pressure as defined in claim 49, wherein the adder/subtractor comprises means for adding the preset increment to the level of positive end expiratory pressure when the signal representative of pre-inspiratory effort Is higher than said given threshold, and means for subtracting the preset decrement from the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is lower than said given threshold.

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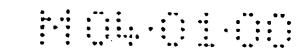
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- 51) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 50, wherein adder/subtractor comprises means for adding the preset increment to or subtracting the preset decrement from one of the following parameters produced by said pressure assist device: a level of air flow, and a level of air volume.
- 52) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein said computer device comprises means for calculating said signal representative of pre-inspiratory effort at said onset time.
- 53) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein said computer device comprises means for calculating said signal representative of pre-inspiratory effort during a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time.
- 54) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein:
  - a) said computer device comprises means for calculating a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time; and
  - b) said adder/subtractor comprises means for adding said preset increment to or for subtracting said preset decrement from the level of positive end expiratory pressure depending on whether said period is higher or lower than a given limit.

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- 55) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 54, wherein said adding/subtracting means comprise means for adding the preset increment to or for subtracting the preset decrement from the level of positive end expiratory pressure depending on both whether said period is higher or lower than a given limit, and whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold.
- 10 56) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 55, further comprising an alarm generator to produce an alarm signal when said signal representative of pre-inspiratory effort is higher or lower than a given threshold.

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- 57) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 56, wherein said adder comprises a manual adjustment system for adding said preset increment to or subtracting said preset decrement from the level of positive end expiratory pressure.
- 58) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 57, comprising means for expressing the signal representative of inspiratory effort as one of the following values: a mean amplitude, a median amplitude, and a peak amplitude.

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59) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 58, wherein the signal representative of inspiratory effort is an electromyographic signal from at least one muscle of a patient.

From the INTERNATIONAL SEARCHING AUTHORITY

To: GOUDREAU GAGE DUBUC & MARTINEAU WALKER

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Attn. Dubuc, J. The Stock Exchange Tower

## PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

P.O.Box 242, Victoria-square Montréal, Québec H4Z 1E9 CANADA	(PCT Rule 44.1)
	Oake of mailing (day/month/year) 06/10/1999
Applicant's or agent's file reference GP/10875.79	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/CA 99/00529	International filing date (day/montr/year) 04/06/1999
Applicant UNIVERSIT DE MONTR AL et al. '	;
The applicant is hereby notified that the International  Filling of amendments and statement under Artic	I Search Report has been established and is transmitted herewith.

1. [	X	The applic	ant is hereby n	offied that the International Search Report has been established and is transmitted herewith.			
				nd statement under Article 18: if he so wishes, to amend the claims of the International Application (see Rule 46):			
		When?	he time limit fonternational Se	or filing such amendments is normally 2 months from the date of transmittal of the earch Report; however, for more details, see the notes on the accompanying sheet.			
		Where?	Directly to the	International Bureau of WIPO 34. chomin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41-22) 740.14.35			
		For more	detailed instru	uctions, see the notes on the accompanying sheet.			
2. [				otified that no International Search Report will be established and that the declaration under ect is transmitted herewith.			
3. [		With rega	rd to the prote	est against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified than			
		he p	cant's request t	with the decision thereon has been transmitted to the International Bureau together with the to forward the texts of both the protest and the decision thereon to the designated Offices.			
		no de	acision has bee	on made yet on the protest; the applicant will be notified as soon as a decision is made.			
4. 1	Furti	her action(	e): The appli	cant is reminded of the following:			
:	Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the international Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.						
'	Withl Wie	n 18 monti has to post	ns from the price	orly date, a demand for international preliminary examination must be filed if the applicant into the national phase until 30 months from the priority date (in some Offices even later).			
•	bef	ore all desi	asomo betano	wity date, the applicant must perform the prescribed acts for entry into the national phase which have not been elected in the demand or in a later election within 19 months from the elected because they are not bound by Chapter II.			

Name and mailing address of the international Searching Authority

European Palent Office, P.B. 5818 Patentiaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016

Nuria Toribio Gonzalez





These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

#### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the International proliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international polication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Prollminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittel of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amandments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the smendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been its filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The smondments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amandments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.



The latter must indicate the differences between the claims as filed and the claims as amended, it must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a slaim as filed.

## The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- (Where originally there were 48 claims and after amendment of some claims there are 51):
   Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by smended claims bearing the same numbers;
   claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11): "Claims 1 to 16 replaced by amended claims 1 to 11."
- (Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims):
   \*Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added.\* or
   \*Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged.\*
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claims 14; claims 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

#### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 600 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

#### Consequence if a demand for international preliminary examination has already been filled

If, at the time of filing any amendments under Article. 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the international Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

#### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.



### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER See Notification (Form PCT/ISA/	of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.
GP/10875.79 International application No.	International filling date (day/month/year)	(Earliest) Priority Date (day/month/year)
	04/06/1999	04/06/1998
PCT/CA 99/00529	04/00/1999	04/00/1990
Applicant		
UNIVERSIT DE MONTR AL et	al.	
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Au ansmitted to the International Bureau.	thority and is transmitted to the applicant.
This International Search Report consists  X It is also accompanied by	of a total of sheets. a copy of each prior art document cited in this	s героп.
1. Basis of the report		
a. With regard to the language, the tanguage in which it was filed, uni	international search was carried out on the baless otherwise indicated under this item.	asis of the International application in the
the international search w Authority (Rule 23.1(b)).	vas carried out on the basis of a translation of	the international application furnished to this
was carried out on the basis of the	nd/or amino acid sequence disclosed in the i e sequence listing : onal application in written form.	international application, the international search
filed together with the inte	rnational application in computer readable for	rm.
limited .	this Authority in written form.	·
	this Authority in computer readble form.	
international application a	psequently furnished written sequence listing as the control of th	
the statement that the info furnished	malo eldabaer retuqmoo ni bebrooer nodamo	is identical to the written sequence listing has been
2. Certain claims were fou	nd unsearchable (See Box I).	
3. Unity of invention is lac	king (see Box II).	·
4. With regard to the title,		
the text is approved as su	ibmitted by the applicant.	
T the text has been establish PROPORTIONNAL PRESSUR ELECTROMYOGRAPHIC SIG	shed by this Authority to read as follows: E ASSIST VENTILATION CONTRONAL	DLLED BY A DIAPHRAGM
5. With regard to the abstract,		
the text is approved as su	ibmitted by the applicant.	
the text has been establish within one month from the	shed, according to Rule 38.2(b), by this Autho a date of mailing of this International search re	nity as it appears in Box III. The applicant may. aport, submit comments to this Authority.
6. The figure of the drawings to be pub		10
as suggested by the appl	Icant.	None of the figures.
because the applicant (al		
because this figure better	r characterizes the invention.	

A. CLASSIFICATION OF SUBJECT MATTER
1PC 6 A61M16/00 A61B5/0488

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELOS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consumed during the international search (name of data base and, where practical, search terms used)

C. DOCUM	ents considered to be relevant	
Category •	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to daim No.
Y	E. AGOSTINI ET AL.: "Electromyography of the diaphragm in man and transdiaphragmatic pressure" JOURNAL OF APPLIED PHYSIOLOGY, vol. 15, 1960, pages 1093-1097, XP002115582 page 1093, left-hand column, line 1 - line 22	1
Y	EP 0 776 671 A (SIEMENS ELEMA AB) 4 June 1997 (1997-06-04) column 2, line 8 - line 41	1
A	US 5 671 752 A (SINDERBY CHRISTER ET AL) 30 September 1997 (1997-09-30) column 10, line 15 - line 18; figure 1 -/	1

Further documents are listed in the continuation of box C.	Patent tamily members are listed in annex.
*Special categories of cited documents:  A* document defining the general state of the art which is not considered to be of particular refevence.  E* earlier document but published on or after the international filling date.  L* document which may throw doubts on priority claim(s) or which is cited to ealablish the publication date of another citation or other special reason (as specified).  *O* document metering to an oral discussure, use, exhibition or other means.  P* document published prior to the international filling date but later than the priority date claimed.	To later document published after the international filling date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention.  "X" occument of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive stap when the document is taken alone cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "8" document member of the same patent family
Oate of the actual completion of the imemational search  17 September 1999	Date of mailing of the International search report  06/10/1999
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentiaan 2  NL - 2280 HV Rijswijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo ni,  Fax: (+31-70) 340-3016	Authorized officer Zeinstra, H

P A 99/00529

		K 99700329
	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to daim No
Category *	Citation of document, with incitation, where appropriate, of the levels in passages	
A	WO 97 22377 A (UNIV MANITOBA ; YOUNES MAGDY (CA)) 26 June 1997 (1997-06-26) page 7, line 4 -page 9, line 28; figure 1	1
A	US 5 353 788 A (MILES LAUGHTON E) 11 October 1994 (1994-10-11)	
P,X	WO 98 48877 A (GRASSINO ALEJANDRO;SINDERBY CHRISTER (SE); FRIBERG SVEN (SE); LIN) 5 November 1998 (1998-11-05) page 10, line 22 -page 11, line 4; figures 1-5 page 16, line 14 -page 17, line 19 page 19, line 16 -page 22, line 4; figure	1
	10	
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I Insecoational Application No

	ď	gallou ou bateur ramily members		/CA 99/00529			
Patent document cited in search report		Publication date		Patent family member(s)		Publication date	
EP 0776671	A	04-06-1997	JP	9173454	Α	08-07-1997	
			บร	5720278	A	24-02-1998	
US 5671752	A	30-09-1997	CA	2172329	A	01-10-1996	
			US	5820560	A	13-10-1998	
WO 9722377		26-06-1997	AU	1090897	Α	14-07-1997	
			CA	2240733	Α	26-06-1997	
			EΡ	0871509	A	21-10-1998	
		•	JP	11502755	T	09-03-1999	
US 5353788	A	11-10-1994	NON	E			
WO 9848877	Α	05-11-1998	US	5820560	Α	13-10-1998	
			AU	3534497	Α	24-11-1998	
			~~~~				



## 09/701824 525 Rec'd PCT/PTO 04 DEC 2000



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140 Grando Alloc Est

Subject:

**European Patent Office** 

D-80298 Munich **GERMANY** 

International Preliminary Examining Authority

International application No. PCT/CA99/00529

International filing date: 04/06/99

Applicant: UNIVERSITÉ DE MONTRÉAL et al.

"PROPORTIONAL PRESSURE ASSIST VENTILATION CONTROLLED BY A DIAPHRAGM ELECTROMYOGRAPHIC

SIGNAL"

Dear Sirs:

This is in response to the Written Opinion dated February 23, 2000.

As indicated in Applicant's letter dated December 30, 1999, a new set of fifty-nine (59) claims were filed in the present patent application.

Please find enclosed herewith a version of these fifty-nine (59) claims indicating the passages of the application as filed on which the new claims are based.

Regarding the amendment to the abstract, the wording of the new abstract is supported by the new wording of the claims.

Regarding the requirements as to the casting of the independent claims in the two-part form and to the insertion of reference numerals in the claims, these modifications will be dealt with during the prosecution of the corresponding EPO regional phase.



We are looking forward to hearing from the Examiner in this matter.

Yours very truly,

**GOUDREAU GAGE DUBUC** 

Gaétan Prince

GP/cm Enclosures

#### **CLAIMS**

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- 1) A method for substantially removing a common noise signal portion (page 17, lines 20-25) from electrical signals produced by an electrical signal source having a polarity reversal region with a centre, said electrical signals having inverse polarities on opposite sides of the centre (page 11, lines 7-16), said method comprising:
  - a) sensing a first electrical signal of a first polarity through first electrodes located on one side of the centre (page 9, lines 10-13; page 10, lines 25-27; page 11, lines 13-16; Figure 4);
- b) sensing a second electrical signal of a second polarity through second electrodes located on the other side of said centre (page 9, lines 10-13; page 10, lines 25-27; page 11, lines 13-16; Figure 4);
  - c) sensing a third electrical signal through third electrodes located between said first electrodes and said second electrodes (page 13, lines 22-24; page 14, lines 10-12);
  - d) combining the first and second electrical signals into a combination signal (page 14, lines 5-8; step 504 of Figure 5; Figure 7); and
  - e) combining the combination signal and the third electrical signal into an output signal (page 14, lines 10-15).
  - 2) A method for substantially removing a common noise signal portion as recited in claim 1, wherein:
    - said first and second polarities are opposite polarities (page 11, lines 13-16);
    - combining the first and second electrical signals comprises subtracting one of the first and second electrical signals from the

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other of said first and second electrical signals to produce a combination signal substantially free from said common noise signal portion (page 14, lines 5-8; step 504 of Figure 5); and - combining the combination signal with the third electrical signal comprises adding the combination signal and the third electrical signal to produce said output signal still substantially free from said common noise signal portion and thereby substantially prevent output signal loss (page 14, lines 10-15).

- 3) A method for substantially removing a common noise signal portion as recited in claim 1 or 2, further comprising differentially amplifying said first electrical signal (page 9, lines 4-6), differentially amplifying said second electrical signal (page 9, lines 4-6), and differentially amplifying said third electrical signal (page 9, lines 4-6).
- 4) A method for substantially removing a common noise signal portion as recited in claim 1, 2 or 3, wherein sensing of said first, second and third electrical signals comprises forming with said first, second and third electrodes a series of electrodes having an axis extending through the centre of the polarity reversal region substantially in the direction of polarity reversal (12 of Figures 1, 2 and 3; page 8, lines 1-6; page 11, lines 7-16).
  - 5) A method for substantially removing a common noise signal portion as recited in claim 1, 2, 3 or 4, further comprising applying said output signal substantially free from said common noise signal portion to a ventilatory assistance system (page 16, lines 12-25).

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- 6) A method for substantially removing a common noise signal portion as recited in claim 1, 2, 3, 4 or 5, wherein sensing of said first, second and third electrical signals comprises sensing first, second and third electromyographic signals, respectively, from at least one muscle of a patient, said at least one muscle constituting the electrical signal source (page 8, lines 1-6 and 27; page 9, lines 10-13).
- 7) A device for substantially removing a common noise signal portion (page 17, lines 20-25) from electrical signals produced by an electrical signal source having a polarity reversal region with a centre, said electrical signals having inverse polarities on opposite sides of the centre (page 11, lines 7-16), said device comprising:
  - a) a first input responsive to a first electrical signal having a first polarity sensed through first electrodes located on one side of the centre (page 9, lines 10-13; page 10, lines 25-27; page 11, lines 13-16; Figure 4);
  - a second input responsive to a second electrical signal having a second polarity sensed through second electrodes located on the other side of said centre (page 9, lines 10-13; page 10, lines 25-27; page 11, lines 13-16; Figure 4);
  - c) a third input responsive to a third electrical signal sensed through third electrodes located between the first electrodes and the second electrodes (page 13, lines 22-24; page 14, lines 10-12);
  - d) means for combining the first and second electrical signals into a combination signal (page 14, lines 5-8; step 504 of Figure 5; Figure 7); and
  - e) means for combining the combination signal and the third electrical signal into an output signal (page 14, lines 10-15).

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- 8) A device for substantially removing a common noise signal portion as recited in claim 7, wherein:
  - said first and second polarities are opposite polarities (page 11, lines 13-16);
  - the first and second electrical signals combining means comprises means for subtracting one of the first and second electrical signals from the other of said first and second electrical signals to produce a combination signal substantially free from said common noise signal portion (page 14, lines 5-8; step 504 of Figure 5); and
  - the means for combining the combination signal with the third electrical signal comprises means for adding the combination signal and the third electrical signal to produce said output signal still substantially free from said common noise signal portion and thereby substantially prevent output signal loss (page 14, lines 10-15).
- 9) A device for substantially removing a common noise signal portion as recited in claim 7 or 8, further comprising a first differential amplifier for amplifying said first electrical signal (page 9, line 4-6; 16 of Figure 1), a second differential amplifier for amplifying said second electrical signal (page 9, line, 4-6; 16 of Figure 1), and third differential amplifier for amplifying said third electrical signal (page 9, line 4-6; 16 of Figure 1).
- 10) A device for substantially removing a common noise signal portion as recited in claim 7 or 8, wherein said first, second and third electrodes form a series of electrodes having an axis extending through the center of the polarity reversal region substantially in the direction of polarity

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reversal (12 of Figures 1, 2 and 3; page 8, lines 1-6; page 11, lines 7-16).

- 11) A device for substantially removing a common noise signal portion as recited in claim 7, 8 or 9, further comprising a ventilatory assistance system to which is supplied said output signal substantially free from said common noise signal portion (page 16, lines 12-25).
- 12) A device for substantially removing a common noise signal portion as recited in claim 7, 8, 9, 10 or 11, further comprising means for extracting from said first, second and third electrical signals, a first, second and third electromyographic signals from at least one muscle of a patient, said at least one muscle constituting said electrical signal source (page 8, lines 1-6 and 27; page 9, lines 10-13).
- 13) A neuro-ventilatory efficiency computation method (page 19, lines 24-27) for monitoring/controlling the level of ventilatory assist produced by a ventilatory assistance system (page 21, lines 5-17), comprising:
  - a) receiving a first signal representative of inspiratory effort and having a first amplitude (page 19, lines 25-27; signal 508 in Figure 10);
  - b) receiving a second signal representative of a lung volume and having a second amplitude (page 19, lines 24-27; see also the "given inspiratory lung volume" signal of Figure 10);
  - c) calculating a relation between said first and second amplitudes at predetermined intervals (page 19, line 27 and page 20, line 1; page 20, lines 19-22; page 20, lines 26 and 27; and block 602 of Figure 10); and

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- d) increasing (page 20, lines 3-10; block 606 of Figure 10) or decreasing (page 20, lines 12-18; block 608 of Figure 10) the ventilatory assist level depending on whether a present calculated value of said relation is higher (page 20, lines 3-7; block 603 of Figure 10) or lower (page 20, lines 12-15; block 607 of Figure 10) than a past calculated value of said relation by an amount exceeding a given threshold.
- 14) A neuro-ventilatory efficiency computation method as in claim 13, wherein said relation calculating comprises calculating a ratio between said first and second amplitudes at predetermined time intervals (page 18, line 6 to page 19, line 17).
- 15) A neuro-ventilatory efficiency computation method as in claim 13, wherein said relation calculating comprises calculating a ratio between said first and second amplitudes at intervals when one of said first and second amplitudes reaches a predetermined level (page 23, lines 9-23).
- 16) A neuro-ventilatory efficiency computation method as in claim 13, 14 or 15, wherein the ventilatory assist level increasing or decreasing comprises increasing the ventilatory assist level when said present calculated value of said relation is higher than said past calculated value of said relation by an amount exceeding the given threshold (page 20, lines 3-10), and decreasing the ventilatory assist level when said present calculated value of said relation is lower than said past calculated value of said relation by an amount exceeding said given threshold (page 20, lines 12-22).

17) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15 or 16, wherein receiving the second signal representative of a lung volume comprises receiving a signal representative of a given lung volume (page 19, lines 19-21 and 26-27; see "given inspiratory lung volume" signal supplied to block 601 of Figure 10).

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18) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16 or 17, wherein receiving the first signal representative of inspiratory effort comprises receiving a signal representative of a given level of inspiratory effort (page 19, lines 21-22).

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- 19) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17 or 18, further comprising generating an alarm signal when said present calculated value of said relation is higher or lower than the past calculated value of said relation by an amount exceeding said given threshold (page 20, lines 2-24).
- 20) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, or 19, comprising manually performing said increasing or decreasing of the ventilatory assist level (page 20, lines 22-24; page 21, lines 2-4).
- 21) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19 or 20, comprising expressing the first signal representative of inspiratory effort as one of the following values: a mean of said first amplitude, a median of said first amplitude, and a peak of said first amplitude (page 20, lines 1-4).

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- A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19 or 20, comprising expressing the second signal representative of a lung volume as one of the following values: a mean of said second amplitude, a median of said second amplitude, and a peak of said second amplitude (page 19, lines 21-22; and page 20, lines 1-4).
- 23) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22 wherein receiving the first signal representative of inspiratory effort comprises receiving an electromyographic signal from at least one muscle of a patient ( page 19, lines 26-27; and signal 508 of Figure 10).
- 24) A neuro-ventilatory efficiency computation device (page 19, lines 24-27) for monitoring/controlling the level of ventilatory assist produced by a ventilatory assistance system (page 21, lines 5-17), comprising:
  - a first input for receiving a first signal representative of inspiratory effort and having a first amplitude (page 19, lines 25-27; signal 508 in Figure 10);
  - b) a second input for receiving a second signal representative of a lung volume and having a second amplitude (page 19, lines 24-27; see also the "given inspiratory lung volume" signal of Figure 10);
  - c) means for calculating a relation between said first and second amplitudes at predetermined intervals (page 19, line 27 and page 20, line 1; page 20, lines 26 and 27; and block 602 of Figure 10); and
  - d) means for increasing (page 20, lines 3-10; block 606 of Figure 10) or decreasing (page 20, lines 12-18; block 608 of Figure 10)

the ventilatory assist level depending on whether a present calculated value of said relation is higher (page 20, lines 3-7; block 603 of Figure 10) or lower (page 20, lines 12-15; block 607 of Figure 10) than a past calculated value of said relation by an amount exceeding a given threshold.

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25) A neuro-ventilatory efficiency computation device as in claim 24, wherein:

the calculating means comprises a divider responsive to the first and second amplitudes for calculating a ratio between said first and second amplitudes at predetermined intervals (page 18, line 6 to page 19, line 17):

the increasing or decreasing means comprises:

- a comparator responsive to the present calculated value and the past calculated value of said relation for producing a signal representative of a comparison between a present calculated value of said relation and a past calculated value of said relation (page 20, lines 2-22);
- an adder interposed between the comparator and the ventilatory assistance system for adding a preset increment to or subtracting a preset decrement from said ventilatory assist level when the comparison signal exceeds a given threshold (page 20, lines 2-22).
- 26) A neuro-ventilatory efficiency computation device as in claim 24 or 25, wherein said calculating means comprises means for calculating said relation at predetermined time intervals (page 18, line 6 to page 19, line 17).

27) A neuro-ventilatory efficiency computation device as in claim 24, or 25, wherein said calculating means comprises means for calculating said relation at intervals when one of said first and second amplitudes reach a predetermined level (page 23, lines 9-23).

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28) A neuro-ventilatory efficiency computation device as in any one of claims 25 to 27, wherein said adder comprises means for adding said preset increment to said ventilatory assist level when said present calculated value of said relation is higher than said past calculated value of said relation by an amount exceeding said given threshold (page 20. lines 2-22), and means for subtracting said preset decrement from said ventilatory assist level when said present calculated value of said relation is lower than said past calculated value of said relation by an amount exceeding said given threshold (page 20, lines 2-22).

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- 29) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 28, wherein the second signal representative of a lung volume is a signal representative of a given lung volume (page 19, lines 19-21 and 26-27; see "given inspiratory lung volume" signal supplied to block 601 of Figure 10).
- 30) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 28, wherein the second signal representative of inspiratory effort is a signal representative of a given level of inspiratory effort (page 19, lines 21-22).



31) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 30, further comprising an alarm generator to produce an alarm signal when said present calculated value of said relation is higher or lower than the past calculated value of said relation by an amount exceeding said given threshold (page 20, lines 2-24).

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- A neuro-ventilatory efficiency computation device as in any one of claims 24 to 31, wherein said adder comprises a manual adjustment system to add said preset increment to or subtracting said preset decrement from said ventilatory assist level (page 20, lines 22-24; page 21, lines 2-4).
- 33) A neuro-ventilatory efficiency computation device as in any one of claims 22 to 32, comprising means for expressing the first signal representative of inspiratory effort by means of one of the following values: a mean of said first amplitude, a median of said first amplitude, and a peak of said first amplitude (page 20, lines 1-4).
- 34) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 32, further comprising means for expressing the second signal representative of a lung volume by means of one of the following values: a mean of said second amplitude, a median of said second amplitude, and a peak of said second amplitude (page 19, lines 21-22; and page 20, lines 1-4).
- 25 35) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 34, wherein the first signal representative of inspiratory effort

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is an electromyographic signal from at least one muscle of a patient (page 19, lines 25-27; and signal 508 of Figure 10).

- 36) A method for monitoring/adjusting the level of positive end expiratory pressure produced by a pressure assist device (page 3, line 24 to page 4, line 8; page 21, line 21 to page 24, line 3) in relation to a signal representative of inspiratory effort (page 22, lines 20-22; see also signal 508 in Figure 11) in view of minimizing the level of pre-inspiratory effort (page 4, lines 2-4), comprising:
  - a) receiving a signal representative of inspiratory flow (page 22 line24 to page 23, line 2; see signal 703 in Figure 11);
  - b) calculating from said inspiratory flow signal an onset time for inspiration (page 23, lines 3-7; block 704 of Figure 11);
  - c) receiving a signal representative of inspiratory effort having an amplitude (page 22, lines 20-22; signal 508 in Figure 11);
- d) calculating a signal representative of pre-inspiratory effort in response to said onset time and said signal representative of inspiratory effort (page 23, lines 9-13; blocks 713 and 714 in Figure 11); and
  - e) increasing (page 23, lines 9-15; blocks 715, 716 and 708 of Figure 11) or decreasing (page 23, lines 17-23; blocks 719, 720 and 711) the level of positive end expiratory pressure in relation to sald signal representative of pre-inspiratory effort.
- 37) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 36, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure

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depending on whether the amplitude of said signal representative of preinspiratory effort is higher or lower than a given threshold (page 23, lines 9-23; blocks 715-716-708 and 719-720-711 of Figure 11).

- as) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 37, wherein increasing of decreasing the level of positive end expiratory pressure comprises increasing the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is higher than said given threshold (page 23, lines 9-15; blocks 715-716-708 of Figure 11), and decreasing the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is lower than said given threshold (page 23, lines 17-23; blocks 719-720-711 of Figure 11).
- 39) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 38, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing one of the following parameters produced by said pressure assist device: a level of air flow, and a level of air volume (page 24, lines 4-7).
  - 40) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein calculating said signal representative of pre-inspiratory effort comprises calculating said signal representative of pre-inspiratory effort at said onset time (page 23, lines 9-11).

- 41) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein calculating said signal representative of pre-inspiratory effort comprises calculating said signal representative of pre-inspiratory effort during a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time (page 22, lines 11-15).
- 42) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein:
- a) calculating said signal representative of pre-inspiratory effort comprises calculating a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time (page 22, lines 11-15; page 23, lines 3-7; block 704 of Figure 11); and
- b) increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on whether said period is higher or lower than a given limit (page 23, lines 25-27).
- 43) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 39, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on both whether said period is higher or lower than the given limit, and whether the amplitude of the signal representative of pre-inspiratory effort is higher or lower than a given threshold (page 23, lines).

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9-27; blocks 715-716-708 of Figure 11; and blocks 719-720-711 of Figure 11).

- 44) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 43, further comprising generating an alarm signal when said signal representative of pre-inspiratory effort is higher or lower than a given threshold (page 23, lines 9-23; block 716 and 720 of Figure 11).
- 45) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 44, comprising manually performing the increase or decrease of the level of positive end expiratory pressure (page 23, lines 15 and 23).
- 46) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 45, comprising expressing said signal representative of inspiratory effort as one of the following values: a mean amplitude, a median amplitude, and a peak amplitude (block 714 of Figure 11).
- 47) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 46, wherein receiving said signal representative of inspiratory effort comprises receiving an electromyographic signal from at least one muscle of a patient (page 22, lines 20-22; signal 508 of Figure 11).
  - 48) A controller for monitoring/adjusting the level of positive end expiratory pressure produced by a pressure assist device (page 3, line

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24 to page 4, line 8; page 21, line 21 to page 24, line 3) in relation to a signal representative of inspiratory effort (page 22, lines 20-22; see also signal 508 of Figure 11) in view of minimizing the level of pre-inspiratory effort (page 4, line 2-4), comprising:

- a) a first input for receiving a signal representative of inspiratory flow having an onset time for inspiration (page 22, line 24 to page 23, line 2; see signal 703 of Figure 11);
- b) a second input for receiving a signal representative of inspiratory effort having an amplitude (page 22, lines 20-22; signal 508 of Figure 11);
- c) a computer device responsive to said onset time and said signal representative of inspiratory effort to compute said signal representative of pre-inspiratory effort (page 23, lines 9-13; blocks 713 and 714 of Figure 11); and
  - d) an adder/substractor for adding a preset increment to (page 23, lines 9-15; blocks 715-716-708 of Figure 11) or subtracting a preset decrement from (page 23, lines 17-23; blocks 719-720-711 of Figure 11) the level of positive end expiratory pressure in relation to said signal representative of pre-inspiratory effort.
- 49) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 48, wherein the adder/subtractor comprises means for adding the preset increment to or for subtracting the preset decrement from the level of positive end expiratory pressure depending on whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold (page 23, lines 9-23; blocks 715-716-708 of Figure 11; and blocks 719-720-711 of Figure 11).

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- 50) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 49, wherein the adder/subtractor comprises means for adding the preset increment to the level of positive end expiratory pressure when the signal representative of pre-inspiratory effort is higher than said given threshold (page 23, lines 9-15; blocks 715-716-708 of Figure 11), and means for subtracting the preset decrement from the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is lower than said given threshold (page 23, lines 17-23; blocks 719-720-711 of Figure 11).
- 51) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 50, wherein adder/subtractor comprises means for adding the preset increment to or subtracting the preset decrement from one of the following parameters produced by said pressure assist device: a level of air flow, and a level of air volume (page 24, lines 4-7).
- 52) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein said computer device comprises means for calculating said signal representative of pre-inspiratory effort at said onset time (page 23, lines 9-11).
- 53) A controller for monitoring/adjusting the level of positive end
  expiratory pressure as defined in any one of claims 48 to 51, wherein said
  computer device comprises means for calculating said signal
  representative of pre-inspiratory effort during a period between the time

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when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time.

- 54) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein:
  - a) sald computer device comprises means for calculating a period between the time when sald signal representative of inspiratory effort reaches a minimum amplitude and sald onset time (page 22, lines 11-15; page 23, lines 3-7; and block 704 of Figure 11); and
  - b) said adder/subtractor comprises means for adding said preset increment to or for subtracting said preset decrement from the level of positive end expiratory pressure depending on whether said period is higher or lower than a given limit (page 23, lines 25-27).
- 55) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 54, wherein said adding/subtracting means comprise means for adding the preset increment to or for subtracting the preset decrement from the level of positive end expiratory pressure depending on both whether said period is higher or lower than a given limit, and whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold (page 23, lines 9-27; blocks 715-716-708 of Figure 11; and blocks 719-720-711 of Figure 11).
- 56) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 55, further

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comprising an alarm generator to produce an alarm signal when said signal representative of pre-inspiratory effort is higher or lower than a given threshold (page 23, lines 9-23; blocks 716 and 720 of Figure 11).

- 57) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 56, wherein said adder comprises a manual adjustment system for adding said preset increment to or subtracting said preset decrement from the level of positive end expiratory pressure (page 23, lines 15 and 23).
- 10 58) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 57, comprising means for expressing the signal representative of inspiratory effort as one of the following values: a mean amplitude, a median amplitude, and a peak amplitude (block 714 of Figure 11).
  - 59) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 58, wherein the signal representative of inspiratory effort is an electromyographic signal from at least one muscle of a patient (page 22, lines 20-22; signal 508 of Figure 11).



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Subject:

International Application No. PCT/CA99/00529

International filing date: June 04, 1999

Applicant: UNIVERSITÉ DE MONTRÉAL et al.

Dear Sir/Madam:

Please find enclosed herewith an amendment under Article 34.

This amendment includes new pages 25 to 41 including a new set of 59 claims. This new set of claims replaces the originally filed single claim 1. New claim 13 is an amended version of original single claim 1.

A new page 42 is also attached and contains a new abstract better reflecting the subject matter of the newly submitted set of claims.

We are looking forward to receiving a written opinion in due course.

Yours very truly.

Goudreau Gage Dubuc & Martineau Walker

Gaétan Prince

GP/CMB/mt Encl.

#### **CLAIMS**

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- 1) A method for substantially removing a common noise signal portion from electrical signals produced by an electrical signal source having a polarity reversal region with a centre, said electrical signals having inverse polarities on opposite sides of the centre, said method comprising:
  - a) sensing a first electrical signal of a first polarity through first electrodes located on one side of the centre;
  - b) sensing a second electrical signal of a second polarity through second electrodes located on the other side of said centre;
  - c) sensing a third electrical signal through third electrodes located between said first electrodes and said second electrodes;
  - d) combining the first and second electrical signals into a combination signal; and
- e) combining the combination signal and the third electrical signal into an output signal.
- 2) A method for substantially removing a common noise signal portion as recited in claim 1, wherein:
  - said first and second polarities are opposite polarities;
  - combining the first and second electrical signals comprises subtracting one of the first and second electrical signals from the other of said first and second electrical signals to produce a combination signal substantially free from said common noise signal portion; and
  - combining the combination signal with the third electrical signal comprises adding the combination signal and the third electrical

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signal to produce said output signal still substantially free from said common noise signal portion and thereby substantially prevent output signal loss.

- 3) A method for substantially removing a common noise signal portion as recited in claim 1 or 2, further comprising differentially amplifying said first electrical signal, differentially amplifying said second electrical signal, and differentially amplifying said third electrical signal.
- 4) A method for substantially removing a common noise signal portion as recited in claim 1, 2 or 3, wherein sensing of said first, second and third electrical signals comprises forming with said first, second and third electrodes a series of electrodes having an axis extending through the centre of the polarity reversal region substantially in the direction of polarity reversal.
  - 5) A method for substantially removing a common noise signal portion as recited in claim 1, 2, 3 or 4, further comprising applying said output signal substantially free from said common noise signal portion to a ventilatory assistance system.
  - 6) A method for substantially removing a common noise signal portion as recited in claim 1, 2, 3, 4 or 5, wherein sensing of said first, second and third electrical signals comprises sensing first, second and third electromyographic signals, respectively, from at least one muscle of a patient, said at least one muscle constituting the electrical signal source.

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- 7) A device for substantially removing a common noise signal portion from electrical signals produced by an electrical signal source having a polarity reversal region with a centre, said electrical signals having inverse polarities on opposite sides of the centre, said device comprising:
- a) a first input responsive to a first electrical signal having a first polarity sensed through first electrodes located on one side of the centre;
  - b) a second input responsive to a second electrical signal having a second polarity sensed through second electrodes located on the other side of said centre;
  - c) a third input responsive to a third electrical signal sensed through third electrodes located between the first electrodes and the second electrodes;
  - d) means for combining the first and second electrical signals into a combination signal; and
- e) means for combining the combination signal and the third electrical signal into an output signal.
  - 8) A device for substantially removing a common noise signal portion as recited in claim 7, wherein:
    - said first and second polarities are opposite polarities;
    - the first and second electrical signals combining means comprises means for subtracting one of the first and second electrical signals from the other of said first and second electrical signals to produce a combination signal substantially free from said common noise signal portion; and
    - the means for combining the combination signal with the third electrical signal comprises means for adding the combination

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signal and the third electrical signal to produce said output signal still substantially free from said common noise signal portion and thereby substantially prevent output signal loss.

- 9) A device for substantially removing a common noise signal portion as recited in claim 7 or 8, further comprising a first differential amplifier for amplifying said first electrical signal, a second differential amplifier for amplifying said second electrical signal, and third differential amplifier for amplifying said third electrical signal.
- 10) A device for substantially removing a common noise signal portion as recited in claim 7 or 8, wherein said first, second and third electrodes form a series of electrodes having an axis extending through the center of the polarity reversal region substantially in the direction of polarity reversal.
  - 11) A device for substantially removing a common noise signal portion as recited in claim 7, 8 or 9, further comprising a ventilatory assistance system to which is supplied said output signal substantially free from said common noise signal portion.
  - 12) A device for substantially removing a common noise signal portion as recited in claim 7, 8, 9, 10 or 11, further comprising means for extracting from said first, second and third electrical signals, a first, second and third electromyographic signals from at least one muscle of a patient, said at least one muscle constituting said electrical signal source.

- 13) A neuro-ventilatory efficiency computation method for monitoring/controlling the level of ventilatory assist produced by a ventilatory assistance system, comprising:
  - a) receiving a first signal representative of inspiratory effort and having a first amplitude;
- b) receiving a second signal representative of a lung volume and having a second amplitude;
  - c) calculating a relation between said first and second amplitudes at predetermined intervals; and
  - d) increasing or decreasing the ventilatory assist level depending on whether a present calculated value of said relation is higher or lower than a past calculated value of said relation by an amount exceeding a given threshold.
- 14) A neuro-ventilatory efficiency computation method as in claim 13, wherein said relation calculating comprises calculating a ratio between said first and second amplitudes at predetermined time intervals.
  - 15) A neuro-ventilatory efficiency computation method as in claim 13, wherein said relation calculating comprises calculating a ratio between said first and second amplitudes at intervals when one of said first and second amplitudes reaches a predetermined level.
- 16) A neuro-ventilatory efficiency computation method as in claim 13, 14 or 15, wherein the ventilatory assist level increasing or decreasing comprises increasing the ventilatory assist level when said present calculated value of said relation is higher than said past calculated value of said relation by an amount exceeding the given threshold, and

decreasing the ventilatory assist level when said present calculated value of said relation is lower than said past calculated value of said relation by an amount exceeding said given threshold.

- 17) A neuro-ventilatory efficiency computation method as in claim 13,
   14, 15 or 16, wherein receiving the second signal representative of a lung volume comprises receiving a signal representative of a given lung volume.
- 18) A neuro-ventilatory efficiency computation method as in claim 13,
   10 14, 15, 16 or 17, wherein receiving the first signal representative of inspiratory effort comprises receiving a signal representative of a given level of inspiratory effort.
- 19) A neuro-ventilatory efficiency computation method as in claim 13,
   14, 15, 16, 17 or 18, further comprising generating an alarm signal when said present calculated value of said relation is higher or lower than the past calculated value of said relation by an amount exceeding said given threshold.
- 20 20) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, or 19, comprising manually performing said increasing or decreasing of the ventilatory assist level.
- 21) A neuro-ventilatory efficiency computation method as in claim 13,
   25 14, 15, 16, 17, 18, 19 or 20, comprising expressing the first signal representative of inspiratory effort as one of the following values: a mean

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of said first amplitude, a median of said first amplitude, and a peak of said first amplitude.

- 22) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19 or 20, comprising expressing the second signal representative of a lung volume as one of the following values: a mean of said second amplitude, a median of said second amplitude, and a peak of said second amplitude.
- 23) A neuro-ventilatory efficiency computation method as in claim 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22 wherein receiving the first signal representative of inspiratory effort comprises receiving an electromyographic signal from at least one muscle of a patient.
- 24) A neuro-ventilatory efficiency computation device for
   monitoring/controlling the level of ventilatory assist produced by a ventilatory assistance system, comprising:
  - a) a first input for receiving a first signal representative of inspiratory effort and having a first amplitude;
  - b) a second input for receiving a second signal representative of a lung volume and having a second amplitude;
  - c) means for calculating a relation between said first and second amplitudes at predetermined intervals; and
  - d) means for increasing or decreasing the ventilatory assist level depending on whether a present calculated value of said relation is higher or lower than a past calculated value of said relation by an amount exceeding a given threshold.

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25) A neuro-ventilatory efficiency computation device as in claim 24, wherein:

the calculating means comprises a divider responsive to the first and second amplitudes for calculating a ratio between said first and second amplitudes at predetermined intervals;

the increasing or decreasing means comprises:

- a comparator responsive to the present calculated value and the past calculated value of said relation for producing a signal representative of a comparison between a present calculated value of said relation and a past calculated value of said relation; an adder interposed between the comparator and the ventilatory assistance system for adding a preset increment to or subtracting a preset decrement from said ventilatory assist level when the comparison signal exceeds a given threshold.
- 15 26) A neuro-ventilatory efficiency computation device as in claim 24 or 25, wherein said calculating means comprises means for calculating said relation at predetermined time intervals.
- 27) A neuro-ventilatory efficiency computation device as in claim 24, or 25, wherein said calculating means comprises means for calculating said relation, at intervals when one of said first and second amplitudes reach a predetermined level.
- 28) A neuro-ventilatory efficiency computation device as in any one of claims 25 to 27, wherein said adder comprises means for adding said preset increment to said ventilatory assist level when said present calculated value of said relation is higher than said past calculated value

of said relation by an amount exceeding said given threshold, and means for subtracting said preset decrement from said ventilatory assist level when said present calculated value of said relation is lower than said past calculated value of said relation by an amount exceeding said given threshold.

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- 29) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 28, wherein the second signal representative of a lung volume is a signal representative of a given lung volume.
- 10 30) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 28, wherein the second signal representative of inspiratory effort is a signal representative of a given level of inspiratory effort.
  - 31) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 30, further comprising an alarm generator to produce an alarm signal when said present calculated value of said relation is higher or lower than the past calculated value of said relation by an amount exceeding said given threshold.
- 32) A neuro-ventilatory efficiency computation device as in any one of claims 24 to, 31, wherein said adder comprises a manual adjustment system to add said preset increment to or subtracting said preset decrement from said ventilatory assist level.
- 25 33) A neuro-ventilatory efficiency computation device as in any one of claims 22 to 32, comprising means for expressing the first signal representative of inspiratory effort by means of one of the following

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values: a mean of said first amplitude, a median of said first amplitude, and a peak of said first amplitude.

- 34) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 32, further comprising means for expressing the second signal representative of a lung volume by means of one of the following values: a mean of said second amplitude, a median of said second amplitude.
- 35) A neuro-ventilatory efficiency computation device as in any one of claims 24 to 34, wherein the first signal representative of inspiratory effort is an electromyographic signal from at least one muscle of a patient.
  - 36) A method for monitoring/adjusting the level of positive end expiratory pressure produced by a pressure assist device in relation to a signal representative of inspiratory effort in view of minimizing the level of pre-inspiratory effort, comprising:
    - a) receiving a signal representative of inspiratory flow;
    - b) calculating from said inspiratory flow signal an onset time for inspiration;
- c) receiving a signal representative of inspiratory effort having an amplitude;
  - d) calculating a signal representative of pre-inspiratory effort in response to said onset time and said signal representative of inspiratory effort; and
- e) increasing or decreasing the level of positive end expiratory pressure in relation to said signal representative of pre-inspiratory effort.

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- 37) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 36, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold.
- 38) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 37, wherein increasing of decreasing the level of positive end expiratory pressure comprises increasing the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is higher than said given threshold, and decreasing the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is lower than said given threshold.
- 39) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 38, wherein increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing one of the following parameters produced by said pressure assist device: a level of air flow, and a level of air volume.
- 40) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein calculating said signal representative of pre-Inspiratory effort comprises

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calculating said signal representative of pre-inspiratory effort at said onset time.

- 41) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein calculating said signal representative of pre-inspiratory effort comprises calculating said signal representative of pre-inspiratory effort during a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time.
- 10 42) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 39, wherein:
  - a) calculating said signal representative of pre-inspiratory effort comprises calculating a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time; and
  - b) increasing or decreasing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on whether said period is higher or lower than a given limit.

43) A method for monitoring/adjusting the level of positive end

expiratory pressure as defined in claim 39, wherein increasing or decresing the level of positive end expiratory pressure comprises increasing or decreasing the level of positive end expiratory pressure depending on both whether said period is higher or lower than the given limit, and whether the amplitude of the signal representative of pre-inspiratory effort is higher or lower than a given threshold.

44) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 43, further comprising generating an alarm signal when said signal representative of pre-inspiratory effort is higher or lower than a given threshold.

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45) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 44, comprising manually performing the increase or decrease of the level of positive end expiratory pressure.

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46) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 45, comprising expressing said signal representative of inspiratory effort as one of the following values: a mean amplitude, a median amplitude, and a peak amplitude.

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47) A method for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 36 to 46, wherein receiving said signal representative of inspiratory effort comprises receiving an electromyographic signal from at least one muscle of a patient.

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48) A controller for monitoring/adjusting the level of positive end expiratory pressure produced by a pressure assist device in relation to a signal representative of inspiratory effort in view of minimizing the level of pre-inspiratory effort, comprising:

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- a) a first input for receiving a signal representative of inspiratory flow having an onset time for inspiration;
- b) a second input for receiving a signal representative of inspiratory effort having an amplitude;
- c) a computer device responsive to said onset time and said signal representative of inspiratory effort to compute said signal representative of pre-inspiratory effort; and
- d) an adder/substractor for adding a preset increment to or subtracting a preset decrement from the level of positive end explratory pressure in relation to said signal representative of pre-inspiratory effort.
- 49) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 48, wherein the adder/subtractor comprises means for adding the preset increment to or for subtracting the preset decrement from the level of positive end expiratory pressure depending on whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold.
- 50) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 49, wherein the adder/subtractor comprises means for adding the preset increment to the level of positive end expiratory pressure when the signal representative of pre-inspiratory effort is higher than said given threshold, and means for subtracting the preset decrement from the level of positive end expiratory pressure when said signal representative of pre-inspiratory effort is lower than said given threshold.

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- 51) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 50, wherein adder/subtractor comprises means for adding the preset increment to or subtracting the preset decrement from one of the following parameters produced by said pressure assist device: a level of air flow, and a level of air volume.
- 52) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein said computer device comprises means for calculating said signal representative of pre-inspiratory effort at said onset time.
- 53) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein said computer device comprises means for calculating said signal representative of pre-inspiratory effort during a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time.
- 54) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 51, wherein:
  - a) said computer device comprises means for calculating a period between the time when said signal representative of inspiratory effort reaches a minimum amplitude and said onset time; and
  - b) said adder/subtractor comprises means for adding said preset increment to or for subtracting said preset decrement from the level of positive end expiratory pressure depending on whether said period is higher or lower than a given limit.

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- 55) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in claim 54, wherein said adding/subtracting means comprise means for adding the preset increment to or for subtracting the preset decrement from the level of positive end expiratory pressure depending on both whether said period is higher or lower than a given limit, and whether the amplitude of said signal representative of pre-inspiratory effort is higher or lower than a given threshold.
- 10 56) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 55, further comprising an alarm generator to produce an alarm signal when said signal representative of pre-inspiratory effort is higher or lower than a given threshold.
  - 57) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 56, wherein said adder comprises a manual adjustment system for adding said preset increment to or subtracting said preset decrement from the level of positive end expiratory pressure.
  - 58) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 57, comprising means for expressing the signal representative of inspiratory effort as one of the following values: a mean amplitude, a median amplitude, and a peak amplitude.

59) A controller for monitoring/adjusting the level of positive end expiratory pressure as defined in any one of claims 48 to 58, wherein the signal representative of inspiratory effort is an electromyographic signal from at least one muscle of a patient.

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### ABSTRACT OF THE DISCLOSURE

A closed loop system uses a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volume; b) the inspiratory volume for a given EMG intensity; or c) a combination of a) and b); in view of controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical (lung) ventilator. The closed loop ventilator system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level. An alarm can also be used to detect changes in neuroventilatory efficiency in view of performing manual adjustments. This invention also includes a detection and adjustment system for a) determination of pre-inspiratory effort amplitude, and b) determination of pre-inspiratroy effort duration. This system can be used to monitor and/or manually and/or automatically adjust externally applied pressure flow and/or volume in order to determine and control the level of pre-inspiratory effort and/or duration. Finally, the invention describes a system for removing a common noise portion from an electrical signal by detecting, with multiple pairs of electrodes, first, second and third electrical signals from an electrical signal source. The first and second signals being detected from electrode pairs on opposites sides of a polarity reversal center of the electrical signal source, and the third signal being detected from an electrode pair between the first and second pairs. The system then subtracts the second signal from the first signal, and adds the third signal to obtain a substantially noise free signal and thereby substantially prevent signal loss.



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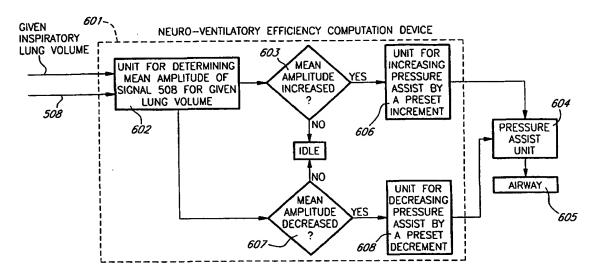
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#### (57) Abstract

A closed loop system uses (a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volume; (b) the inspiratory volume for a given EMG intensity; or (c) a combination of (a) and (b); in view of controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical (lung) ventilator. The closed loop ventilator system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level. An alarm can also be used to detect changes in neuroventilatory efficiency in view of performing manual adjustments.

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PROPORTIONAL PRESSURE ASSIST VENTILATION CONTROLLED BY A DIAPHRAGM ELECTROMYOGRAPHIC SIGNAL

#### BACKGROUND OF THE INVENTION

#### 1. Field of the invention:

The present invention relates to a system using the intensity of the diaphragm electromyogram (EMG) at a given lung volume or the lung volume at a given EMG intensity to automatically or manually adjust the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency.

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The present invention also relates to a system responsive to the intensity of the diaphragm electromyogram (EMG) measured immediately before the onset of inspiratory flow to automatically or manually control and maintain an optimum level of extrinsic positive end expiratory pressure (PEEP) applied to a patient, and to automatically or manually control a duration from the onset of EMG to onset of respiratory flow.

#### 2. Brief description of the prior art:

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Prior art algorithms used to create closed-loop ventilator systems are based on variables such as tidal volume, respiratory rate,

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inspiratory flow, end-tidal carbon dioxide levels and/or rate of rise in pressure. However, none of these parameters can provide a reliable measure of the respiratory neural drive because they are affected by changes in neuro-mechanical or neuro-ventilatory efficiency.

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Neuro-ventilatory efficiency is a term used to express the amount of neural drive (breathing effort) needed to obtain a given tidal lung volume. In brief, neural drive is converted into mechanical tension, a process which is influenced by the muscle length, temperature, electrolyte imbalance, etc. The role of inspiratory flow in the link between neural drive and mechanical tension has previously been suggested; however the proposed influence could not be demonstrated for mean inspiratory flow rates up to 1.4 liters/second. The mechanical tension is then translated into pressure, a process which is affected by the shape of the diaphragm dome. Finally the pressure expands the alveoli and causes air to flow, and the translation of pressure to volume depends on the elasto-viscous behaviour of the respiratory system. Consequently, there are many factors that may influence the tidal volume output obtained for a given increase in neural drive (inspiratory effort).

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Evaluation of respiratory drive by measurements such as the rate of rise in pressure or lung volume is not reliable when, for example, the muscle length or the respiratory system impedance are affected by changes in the neuro-ventilatory efficiency. In a patient, airway resistance and elastance can change from one minute to another and muscle length is continuously altered.

#### OBJECTS AND SUMMARY OF THE INVENTION

An object of the present invention is therefore to eliminate the drawbacks of the prior art.

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Another object of the present invention is to provide a closed loop system using:

- ( a) the intensity of the diaphragm electromyogram (EMG) for a giveninspiratory volume;
  - (b) the inspiratory volume for a given EMG intensity; or
  - (c) a combination of (a) and (b);

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in view of controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical (lung) ventilator; the closed loop ventilator system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level. An alarm can also be used to detect changes in neuroventilatory efficiency in view of performing manual adjustments.

Another object of the present invention is to provide a closed-loop system responsive to the intensity of the diaphragm EMG measured immediately before the onset of inspiratory flow to quantify pre-inspiratory breathing effort in view of automatically or manually adjusting

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a level of extrinsic positive end expiratory pressure (PEEP) applied to a patient in proportion to changes in EMG intensity of pre-inspiratory efforts. In this manner, the pre-ventilatory intensity of the diaphragm EMG can be maintained at a desired, minimum level such that the pre-inspiratory neural drive remains stable at a desired target minimal level. Determination of the duration from the onset of EMG to the onset of respiratory flow is also used for quantitative evaluation of the intrinsic PEEP, and to guide adjustment of the trigger sensitivity of the ventilator systems.

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Different from pressure and ventilatory related indexes, the intensity of the EMG represents the temporal (mean MU (motor unit) rate coding) and spatial (MU recruitment) summation of action potentials and is obtained at the level of the sarcolemma muscle. The intensity of the EMG is therefore not affected by changes in the muscle's neuroventilatory coupling. In the present invention, the use of crural diaphragm EMG rests on the assumption that neural drive to the crural diaphragm is representative for the total respiratory drive. It is also based on the condition that neuromuscular transmission and innervation of the crural diaphragm are normal. For breathing with increased demand this assumption is well founded. Hence, the intensity of the EMG needed to produce a given inspiratory volume should express the efficiency relation between neural drive and volume output.

The objects, advantages and other features of the present invention will become more apparent upon reading of the following non restrictive description of a preferred embodiment thereof,

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given by way of example only with reference to the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

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In the appended drawings:

Figure 1 is a schematic representation of a set-up of an EMG analysis system;

Figure 2 is a section of oesophageal catheter on which an array of electrodes of the EMG analysis system of Figure 1 is mounted;

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Figure 3 illustrates a section of oesophageal catheter on which a second embodiment of the array of electrodes is mounted;

Figure 4 is a graph showing a set of EMG signals of the diaphragm (EMGdi signals) detected by pairs of successive electrodes of the array of Figure 2;

Figure 5 is a flow chart showing a method for conducting a double subtraction technique of the EMGdi signals;

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Figure 6 is a graph showing the distribution of correlation coefficients calculated for determining the position of the center of the

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depolarizing region of the diaphragm along the array of electrodes of Figure 2;

Figure 7 is a schematic diagram illustrating in the time domain a double subtraction technique for improving the signal-to-noise ratio and to reduce an electrode-position-induced filter effect along the array of electrodes of Figure 2;

Figure 8a is a graph showing the power density spectrum of electrode motion artifacts, the power density spectrum of ECG, and the power density spectrum of EMGdi signals;

Figure 8b is a graph showing an example of transfer function for a filter to be used for filtering out the electrode motion artifacts, ECG, and the 50 or 60 Hz disturbance from electrical mains;

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Figure 9 is a schematic diagram illustrating in the frequency domain stabilization by the double subtraction technique of the center frequency upon displacement of the center of the depolarizing region of the diaphragm along the array of electrodes of Figure 2;

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Figure 10 is a schematic block diagram of a system according to the invention for controlling inspiratory assist by means of an EMGdi signal obtained with the above mentioned double subtraction technique and a measurement of the volume of air breathed by the patient by a commercially available system;

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Figure 11 is a schematic block diagram of a system according to the invention (a) capable to determine the time delay from the onset of EMG to the onset of inspiratory flow and (b) using the level of pre-inspiratory effort obtained through the EMGdi signal intensity (common noise level subtracted) during a predetermined time period immediately preceding the onset of inspiratory flow to indicate the presence of "intrinsic PEEP" and to adjust the level of applied "extrinsic PEEP" and/or ventilator trigger sensitivity such that the level of pre-inspiratory effort is suppressed, i.e the EMGdi signal intensity (common noise level subtracted) during the above mentioned predetermined time period is close to zero;

Figure 12a is an exemplary graph of a patient's inspiratory flow versus time for quiet breathing in COPD (Chronic Obstructive Pulmonary Disease); and

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Figure 12b is an exemplary graph of a patient's EMG RMS intensity versus time for quiet breathing in COPD.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Although the preferred embodiment of the present invention will be described in relation to a double subtracted EMGdi signal, it should be kept in mind that the concept of the present invention can be used with any respiratory muscle signal.

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To measure EMG activity of the diaphragm 11 (EMGdi) of a human patient 14, an array of electrodes such as 12 (Figures 1 and 2) are mounted on the free end section 15 of an oesophageal catheter 13, with a constant inter-electrode distance **d** (Figure 2). As shown in Figure 1, the catheter 13 is introduced into the patient's oesophagus through one nostril or the mouth until the array of electrodes 12 is situated at the level of the gastroesophageal junction. The diaphragm 11 and/or the oesophagus slightly move during breathing of the patient 14 whereby the array of electrodes 12 also slightly moves about the diaphragm 11. As will be explained in the following description, automatic compensation for this displacement is provided for.

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According to a preferred embodiment, an electrode 12 is mounted on the free end section 15 of the catheter 13 by winding stainless steel wire (not shown) around that catheter 13. The wound stainless steel wire presents a rough surface smoothed out by solder, which in turn is electroplated with nickel, copper and then gold or silver. Of course, it is within the scope of the present invention to use other electrode structures. Also, the electrodes 12 can possibly be applied to a nasogastric feeding tube (not shown) which is routinely introduced in intensive-care unit (ICU) patients.

Electric wires (not shown) interconnect each pair of successive electrodes such as 1-7 (Figure 2) with a respective one of a group of differential amplifiers 16. Obviously, these electric wires follow the catheter 13 from the respective electrodes 12 to the corresponding amplifiers 16, and are preferably integrated to the catheter 13. Preferably, the electric wires transmitting the EMGdi signals collected by

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the various pairs 1-7 of electrodes 12 are shielded to reduce the influence of external noise, in particular disturbance from the 50 or 60 Hz current and voltage of the electrical mains.

The group of differential amplifiers 16 amplifies (first subtraction step of a so-called double subtraction technique) and bandpass filters each EMGdi signal. This first subtraction step may also be carried out in the personnal computer 19 when the amplifiers 16 are single-ended or equivalently designed amplifiers (monopolar readings).

In the example illustrated in Figures 1 and 2, the free end section 15 of the catheter 13 is provided with an array of eight electrodes 12 defining seven pairs 1, 2, 3, 4, 5, 6 and 7 of successive electrodes 12 respectively collecting seven different EMGdi signals. Although it has been found that EMG activity of the diaphragm (EMGdi) can be measured accurately with an oesophageal catheter 13 provided on the free end section 15 thereof with an array of eight electrodes 12, a different number and/or configuration of pairs of electrodes 12 can be contemplated depending on the patient's anatomy and movement of the diaphragm. Also, the pairs 1-7 do not need to be pairs of successive electrodes; as an example Figure 3 illustrates an array of nine electrodes to form seven overlapping pairs of electrodes 1-7.

A major problem in recording EMGdi signals is to maintain the noise level as low and as constant as possible. Since the electric wires transmitting the EMGdi signals from the electrodes 12 to the differential amplifiers 16 act as an antenna, it is crucial, as indicated in the foregoing description, to shield these electric wires to thereby protect the

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EMGdi signals from additional artifactual noise. Also, the package enclosing the differential amplifiers 16 is preferably made as small as possible (miniaturized) and is positioned in close proximity to the patient to decrease as much as possible the distance between the electrodes 12 and the amplifiers 16.

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The amplified EMGdi signals are sampled by a personal computer 19 through respective isolation amplifiers of a unit 18, to form signal segments of fixed duration. Unit 18 supplies electric power to the various electronic components of the differential and isolation amplifiers while ensuring adequate isolation of the patient's body from such power supply. The unit 18 also incorporates bandpass filters included in the respective EMGdi signal channels to eliminate the effects of aliasing. The successive EMGdi signal segments are then digitally processed into the personal computer 19 after analog-to-digital conversion thereof. This analog-to-digital conversion is conveniently carried out by an analog-to-digital converter implemented in the personal computer 19. The personal computer 19 includes a monitor 40 and a keyboard 31.

It is believed to be within the capacity of those of ordinary skill in the art to construct suitable differential amplifiers 16 and an adequate isolation amplifiers and power supply unit 18. Accordingly, the amplifiers 16 and the unit 18 will not be further described in the present specification.

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An example of the seven EMGdi signals collected by the pairs 1-7 of successive electrodes 12 (Figures 1 and 2) and supplied to the computer 19 is illustrated in Figure 4.

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As the diaphragm is generally perpendicular to the longitudinal axis of the oesophageal catheter 13 equipped with an array of electrodes 12, only a portion of the electrodes 12 are situated in the vicinity of the diaphragm. It is therefore important to determine the position of the diaphragm with respect to the oesophageal electrode array.

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The portion of the crural diaphragm 11 which forms the muscular tunnel through which the oesophageal catheter 13 is passed is referred to the "diaphragm depolarizing region" (DDR). The thickness of the DDR is 20-30 mm. It can be assumed that, within the DDR, the distribution of active muscle fibers has a center from which the majority of the EMGdi signals originate, i.e. the "diaphragm depolarizing region center" (DDR center). Therefore, EMGdi signals detected on opposite sides of the DDR center will be reversed in polarity with no phase shift; in other words, EMGdi signals obtained along the electrode array are reversing in polarity at the DDR center.

Moving centrally from the boundaries of the DDR, EMGdi power spectrums progressively attenuate and enhance in frequency. Reversal of signal polarity on either side of the electrode pair 4 with the most attenuated power spectrum confirms the position from which the EMGdi signals originate, the DDR center.

Referring to Figure 5, the first task of the computer 19 is to determine the position of the center of the DDR along the array of electrodes 12. The center of the DDR is repeatedly determined at predetermined time intervals.

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For that purpose, filtering step 505 removes from each EMGdi signal the motion artifacts, the electrocardiogram (ECG) component, and the disturbance from the electrical mains. Motion artifacts are induced by motion of the electrodes 12. More generally, motion artifacts are defined as a low frequency fluctuation of the EMGdi signals' DC level induced by mechanical alterations of the electrode metal to electrolyte interface i.e. changes in electrode contact area and/or changes in pressure that the tissue exerts on the electrode.

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In step 501, the filtered EMGdi signals from step 505 are cross-correlated in pairs. As well known to those of ordinary skill in the art, cross-correlation is a statistical determination of the phase relationship between two signals and essentially calculates the similarity between two signals in terms of a correlation coefficient **r** (step 502). A negative correlation coefficient **r** indicates that the cross-correlated signals are of opposite polarities.

Figure 6 shows curves of the value of the correlation coefficient **r** versus the midpoint between the pairs of electrodes from which the correlated EMGdi signals originate. In this example, the interelectrode distance is 10 mm. Curves are drawn for distances between the correlated pairs of electrodes 12 of 5 mm (curve 20), 10 mm (curve 21), 15 mm (curve 22) and 20 mm (curve 23). One can appreciate from Figure 5 that negative correlation coefficients **r** are obtained when EMGdi signals from respective electrode pairs situated on opposite sides of the electrode pair 4 are cross-correlated. It therefore appears that the change in polarity occurs in the region of electrode pair 4, which is confirmed by the curves of Figure 4. Accordingly, it can be assumed that

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the center of the DDR is situated substantially midway between the electrodes 12 forming pair 4.

For example, the center of the DDR can be precisely determined by interpolation (step 503 of Figure 5) using a square law based fit of the three most negative correlation coefficients of curve 21 obtained by successive cross-correlation of the EMGdi signal segments from each electrode pair to the EMGdi signal segments from the second next electrode pair. Association of the center of the DDR to a pair of electrodes 12 provides a "reference position" from which to obtain EMGdi signal segments within the DDR. Such control is essential in overcoming the artifactual influence of perpendicular bipolar electrode filtering on the EMGdi power spectrum.

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It has been experimentally demonstrated that EMGdi signals recorded in the oesophagus are satisfactory as long as they are obtained from electrode pairs (with an inter-electrode distance situated between 5 and 20 mm) positioned at a distance situated between 5 and 30 mm on the opposite sides of the DDR center (the inter-pair distance being therefore situated between 5 and 30 mm). Although EMGdi signals obtained from these positions offers a clear improvement in acceptance rate, the signal-to-noise ratio during quiet breathing still tends to remain unsatisfactorily low. The EMGdi signal obtained from one electrode pair (for example channel 0 in Figure 7) situated in between the two electrode pairs used to produce the double subtracted signal, can be added to this double subtracted signal either before as a raw signal or after when RMS or equivalent EMGdi signal measure has been computed, in order to minimize loss of signal.

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For example, in Figure 4, the EMGdi signals originating from the electrode pairs 3 and 5 situated respectively 10 mm below and 10 mm above the DDR are strongly inversely correlated at zero time delay. In contrast to the inversely correlated EMGdi signals, the noise components for electrode pairs 3 and 5 are likely to be positively correlated. Hence, as illustrated in Figure 7, subtraction of the EMGdi signals 24 and 25 from electrode pairs 3 and 5 will result into an addition of the corresponding EMGdi signals (signal 26 of Figure 6) and into a subtraction, that is an elimination of the common noise components. This technique will be referred to as "the double subtraction technique" (step 504 of Figure 5). Again, the EMGdi signal obtained from one electrode pair (for example channel 0 in Figure 7) situated in between the two electrode pairs used to produce the double subtracted signal, can be added to this double subtracted signal either before as a raw signal or after when RMS or equivalent EMGdi signal measure has been computed, in order to minimize loss of signal.

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Subtraction step 504 (second subtraction step of the double subtraction technique) can be carried out either in the time domain, or after conversion of signals 24 and 25 in the frequency domain. Double subtraction technique can be performed by subtracting other combinations of signals, for example by subtracting the EMGdi signal segments from electrode pair 2 from the EMGdi signal segments from electrode pair 5 (Figure 4), by subtracting signal segments from electrode pair 6 from the signal segments from electrode pair 3 and by adding these differences, etc. What is important is to subtract two signals of opposite polarities obtained in the vicinity of the muscle. More than two signal pairs of opposite polarities can be used in the double subtraction. Again,

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the EMGdi signal obtained from one electrode pair (for example channel 0 in Figure 7) situated in between the two electrode pairs used to produce the double subtracted signal, can be added to this double subtracted signal either before as a raw signal or after when RMS or equivalent EMGdi signal measure has been computed, in order to minimize loss of signal.

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The double subtraction technique is carried out in step 504 on the pair of EMGdi signals (for example the signals from electrode pairs 3 and 5 shown in Figure 4) identified in step 503, after appropriate filtering of these EMGdi signals in step 505. Still again, the EMGdi signal obtained from one electrode pair (for example channel 0 in Figure 7) situated in between the two electrode pairs used to produce the double subtracted signal, can be added to this double subtracted signal either before as a raw signal or after when RMS or equivalent EMGdi signal measure has been computed, in order to minimize loss of signal.

The graph of Figure 8a shows the power density spectrum of the above defined electrode motion artifacts, the power density spectrum of ECG, and the power density spectrum of EMGdi signals. The graph of Figure 8b shows an example of transfer function for a filter (the dashed line showing the optimal transfer function, and the solid line the transfer function implemented by the inventors) to be used in step 505 for filtering out the electrode motion artifacts, ECG, and the 50 or 60 Hz disturbance from the electrical mains. Processing of the EMGdi signals by the computer 19 to follow as closely as possible the optimal transfer function of Figure 8b will conduct adequately filtering step 505.

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Therefore, double-subtracted signal segments 509 are obtained at the output of step 504 by subtracting the EMGdi signal segments from the pair of electrodes 12 in optimal location above the diaphragm from the EMGdi signal segments from the pair of electrodes 12 in optimal location below the diaphragm. More than two signal pairs of opposite polarities can be used in the double subtraction. Again, the EMGdi signal obtained from one electrode pair (for example channel 0 in Figure 7) situated in between the two electrode pairs used to produce the double subtracted signal, can be added to this double subtracted signal either before as a raw signal or after when RMS or equivalent EMGdi signal measure has been computed, in order to minimize loss of signal.

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Referring back to Figure 5, step 506 calculates the RMS (root-mean-square) or equivalent or similar value 510 of the double-subtracted signal segments 509 produced in step 504. The increase in intensity obtained with the double subtraction technique is associated with a twofold increase in RMS values. RMS values obtained with the double subtraction technique are closely and linearly related to the original signals. It should be kept in mind that the RMS value can be replaced by any other value representative of the strength of the double-subtracted signal segments 509.

The digital RMS signal segment value 510 calculated by the computer 19 in step 506 is finally digital-to-analog converted to an online analog RMS value 508 (step 507) in view of controlling a lung ventilator 54 (Figure 10). It should be mentioned that it is within the scope of the present invention to supply a digital value 508.

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The double subtraction technique compensates for the changes in signal strength and frequency caused by movement of the diaphragm 11 (Figure 1) and/or the oesophagus during breathing of the patient 14 causing movement of the array of electrodes 12 with respect to the diaphragm 11. Referring to Figure 9, off center of the array of electrodes 12 (electrode-position-induced filter effect) causes a variation of center frequency values due to filtering (see curves 27 and 28) for the EMGdi signals from the electrode pairs 3 and 5. The double subtraction technique eliminates such variation of center frequency values as indicated by curve 29 as well as variation of signal strength. Therefore, the reciprocal influence of the position of the DDR center on the EMGdi signal frequency content is eliminated by the double subtraction technique.

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It has been found that the double subtraction technique may improve the signal-to-noise ratio by more than 2 dB and reduce an electrode-position-induced filter effect. Double subtraction technique is also responsible for a relative increase in acceptance rate by more than 30%.

Noise of non diaphragmatic origin or artifactual signals are strongly correlated at zero time delay and equal in polarity between all pairs of electrodes 12. Hence, this noise of non diaphragmatic origin or artifactual signals appear as a common mode signal for all electrode pairs and therefore, are substantially reduced by the double subtraction technique.

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In the following description, it should be considered that the flow and volume of air breathed by the patient can be measured by any commercially available system.

# **Neuro-ventilatory efficiency:**

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The neuro-ventilatory efficiency is obtained by relating the diaphragm EMGdi signal intensity to changes in lung volume, or by relating the lung volume to changes in diaphragm EMGdi signal intensity. Since the relationship between the diaphragm EMGdi signal intensity and the lung volume is not linear, this non-linearity is minimized by expressing:

- the intensity of the diaphragm EMGdi signal for a given volume change from end-expiratory lung volume, for example the EMGdi signal intensity obtained during 400 ml inspiration starting from end-expiratory lung volume (in the present disclosure, intensity is intended to encompass the mean, peak, median and total RMS intensity of the diaphragm EMGdi signal); or
- 20 the lung volume obtained at a given diaphragm EMGdi signal intensity.

A relatively small tidal lung volume is suitable because the relationship between diaphragm EMGdi signal intensity and lung volume is relatively linear at this low range. Secondly, the use of a fixed, given tidal volume or diaphragm EMGdi signal intensity will protect against the non-linear influences and allows for a reliable estimation of relative changes in neuro-ventilatory efficiency.

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In this manner, a ventilatory efficiency index expressing:

- the EMGdi signal intensity for a given inspiratory lung volume starting from the end-expiratory lung volume; or
- 5 the lung volume for a given diaphragm EMGdi signal intensity;

is calculated. If the EMGdi signal intensity for the above mentioned given inspiratory lung volume or the lung volume for the above mentioned given diaphragm EMGdi signal intensity is changing, the above indicated index will also change and this change can be expressed in percentage (%). For example, using the diaphragm EMGdi signal intensity for the above mentioned fixed, given inspiratory lung volume, an increased EMGdi signal intensity for the above mentioned given inspiratory lung volume will increase the index but will express a reduction in the neuro-ventilatory efficiency, and a decreased EMGdi signal intensity for that given inspiratory lung volume will reduce the index but will express an improvement of the neuro-ventilatory efficiency.

In the following description, an example using the EMGdi signal intensity for a fixed, given inspiratory lung volume will be given. However, it is within the scope of the present invention to use the lung volume for a fixed, given diaphragm EMGdi signal intensity.

Referring now to Figure 10 a preferred, practical embodiment is described. A neuro-ventilatory efficiency computation device 601 receives the signal 508 of Figure 5 as well as the given, fixed inspiratory lung volume. Device 601 comprises a unit 602 for determining

WO 99/62580 PCT/CA99/00529

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the intensity of the signal 508 for the given inspiratory lung volume. Although it is not illustrated, it is within the scope of the present invention to calculate, in unit 602, the peak, mean, median or any other intensity measure of signal 508 for the given inspiratory lung volume. If the intensity of signal 508 for the given inspiratory lung volume has increased at least by a given percentage (step 603), i.e. the neuro-ventilatory efficiency index has increased at least by said given percentage, the pressure, flow, or volume assist unit 604 is controlled by a unit 606 in view of increasing the magnitude of the pressure assist to the patient by a preset increment until the intensity of the signal 508 for the given inspiratory lung volume is restored to a predetermined, preset value.

Still referring to Figure 10, if the intensity for the given inspiratory lung volume has decreased at least by a given percentage (step 607), i.e. the neuro-ventilatory efficiency index has decreased at least by said given percentage, the pressure assist unit 604 is controlled by the unit 608 in view of decreasing the magnitude of the pressure assist by a preset increment until the intensity of the signal 508 for the given inspiratory lung volume is restored to the predetermined, preset value. Although it is not illustrated, it is within the scope of the present invention to calculate, in unit 602, the peak, mean, median or any other intensity measure of signal 508 for the given inspiratory lung volume, instead of the intensity of this signal. Also, the signals at the outputs of the units 606 and 608 can be used to generate an alarm or to manually adjust the pressure, flow or volume assist to the patient.

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The response time is adjustable. The time base used to calculate trends in the EMG intensity for a given volume or vice versa

WO 99/62580 PCT/CA99/00529

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and used for the corrections is relatively slow (minutes) and the levels of applied support can be limited within a safe range. Again, an alarm can be generated or the pressure assist can be manually or automatically adjusted.

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The pressure, flow, or volume assist unit 604 can be any device which can be controlled to generate any airway pressure of adjustable magnitude, for example any source of compressed gas, or a flow or volume pump. Of course, airway 605 refers to or, to the least, includes the patient's respiratory airway.

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In this manner, the pressure assist unit 604 provides a pressure, flow, or volume assist that is adjusted in proportion to changed in neuro-ventilatory efficiency which is the EMGdi signal intensity at a given lung volume or vice versa. The pressure, flow, or volume assist unit continuoulsy operates to maintain a tracheal pressure, flow or volume that is adjusted in proportion to changes in neuro-ventilatory efficiency which is the EMGdi signal intensity at a given lung volume or vice versa.

### **Pre-inspiratory breathing effort:**

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A common problem with mechanically ventilated patients is that the patients' inspiratory effort will not immediately cause an inspiratory airflow so called "intrinsic PEEP" or "auto PEEP" which leads to a decrease in the neuro-ventilatory efficiency. The effect of "intrinsic PEEP" can be counteracted by the application of an "extrinsic PEEP". However, there are no easy applicable techniques to determine when the applied level of "extrinsic PEEP" is adequate. The level of pre-inspiratory

WO 99/62580 PCT/CA99/00529

22

effort obtained through the EMGdi signal intensity (common noise level subtracted) during for example a 100 milliseconds (ms) period immediately preceding the onset of inspiratory flow can be used to indicate the presence of "intrinsic PEEP", and the level of applied "extrinsic PEEP" can be adjusted such that the level of pre-inspiratory effort is suppressed i.e the EMGdi signal intensity (common noise level subtracted) during the above mentioned 100 ms period before onset of inspiratory flow is close to zero. A feedback loop can then be used to maintain the level of pre-inspiratory effort suppressed by adjusting as explained above the level of "extrinsic PEEP".

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Just a word to mention that the above mentioned period of 100 ms can be replaced by a longer or shorter time period immediately preceding the onset of inspiratory flow or by the neuro-ventilatory delay 800 (Figure 12b), i.e. the time period between the onset of EMG 801 (Figure 12b) and the onset of inspiratory flow 802 (Figure 12a).

Figure 11 of the appended drawings illustrates a preferred, practical embodiment 700.

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In the embodiment 700, an integrator 713 is responsive to the RMS EMG signal 508 to continuously calculate the EMG intensity for the above mentioned 100 ms period or neuro-ventilatory delay 800.

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Embodiment 700 also comprises an inspiratory flow detector 702 responsive to the patient's inspiratory flow 703 measured, as indicated in the foregoing description, through any commercially 5

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available system, to produce an output signal 705 representative of EMG activity.

The embodiment 700 of Figure 11 also comprises a neuro-ventilatory delay calculator 704 responsive to (a) the detection of a RMS EMG signal intensity higher than the common noise level (5%), and (b) the detection of the onset of inspiratory flow by the detector 702 to calculate the neuro-ventilatory delay 800 (Figure 12b).

A detector 714 is responsive to the EMG intensity calculated by the integrator 713 to detect the level of EMG intensity 803 (Figure 12b) at the onset of inspiratory flow 802 (Figure 12a) to trigger an alarm 716 when the level of the EMG intensity 803 at the onset of inspiratory flow 802 is higher than a given limit (detector 715). Upon triggering of the alarm 716, the level of applied "extrinsic PEEP" is either automatically or manually increased (device 708).

The detector 714 is responsive to the EMG intensity calculated by the integrator 713 to detect the level of EMG intensity 803 (Figure 12b) at the onset of inspiratory flow 802 (Figure 12a) to trigger an alarm 720 when the level of the EMG intensity 803 at the onset of inspiratory flow 802 is lower than a given limit (detector 719). Upon triggering of the alarm 720, the level of applied "extrinsic PEEP" is either automatically or manually decreased (device 711).

It should be mentioned that feedback from the neuroventilatory delay or pre-inspiratory EMG activity can also be used to adjust the sensitivity of the ventilators trigger functions. Again, the time base used for these corrections is preferably relatively slow (minutes) and the levels of "extrinsic PEEP" can be limited within a safe range.

The pressure assist unit 604 can be any device which can be controlled to generate any airway flow and/or pressure of adjustable magnitude, for example any source of compressed gas, or a flow or volume pump.

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In this manner, the delay from the beginning of the mechanically ventilated patients' inspiratory effort to the onset of the inspiratory assist will be minimized.

Although the present invention has been described hereinabove with reference to preferred embodiments thereof, these embodiments can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the subject invention.

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#### **CLAIMS**

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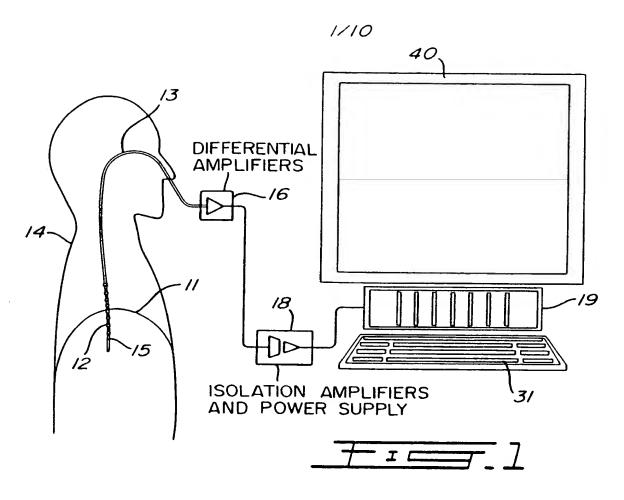
1. A closed loop system for controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical lung ventilator, comprising:

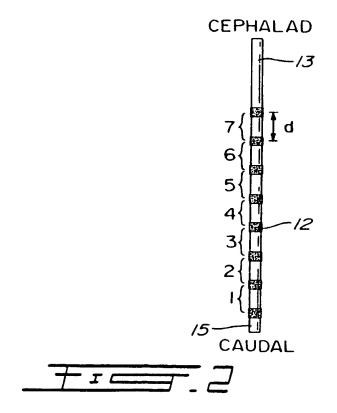
means for measuring (a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volume, (b) the inspiratory volume for a given EMG intensity, and/or (c) a combination of (a) and (b); and

means for controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical lung ventilator in response to measurement of (a) the intensity of the diaphragm electromyogram (EMG) for a given inspiratory volume, (b) the inspiratory volume for a given EMG intensity, and/or (c) the combination of (a) and (b);

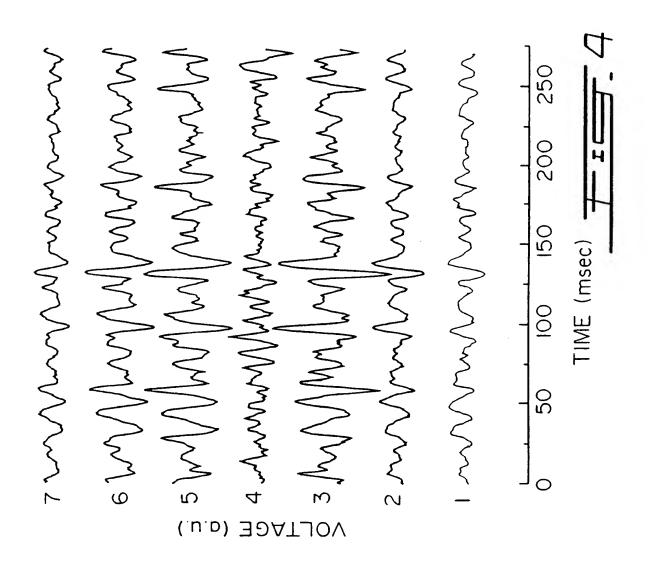
wherein the closed loop system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level.

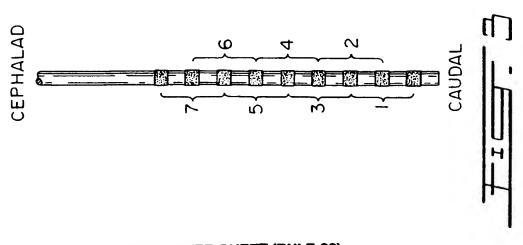
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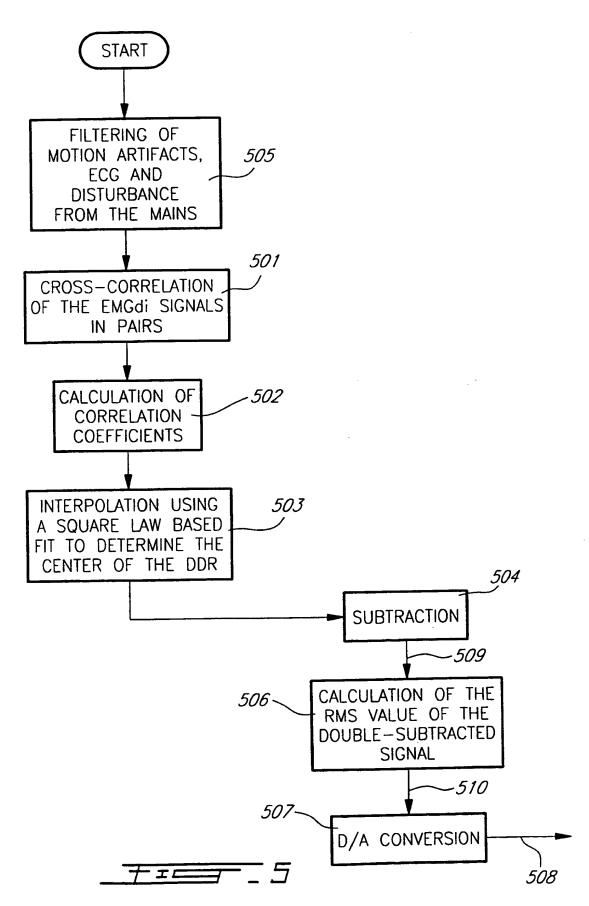


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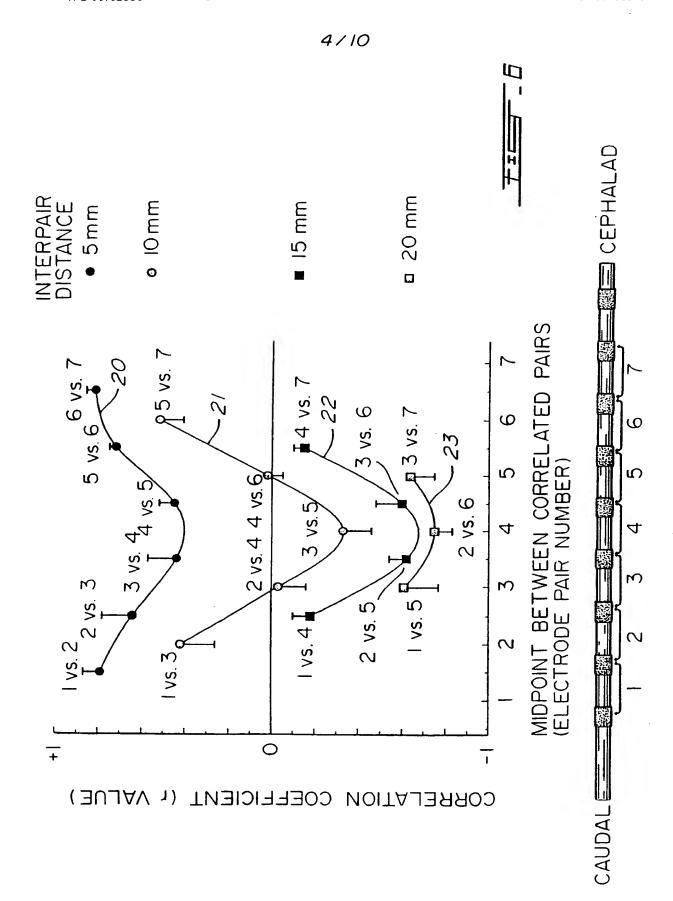


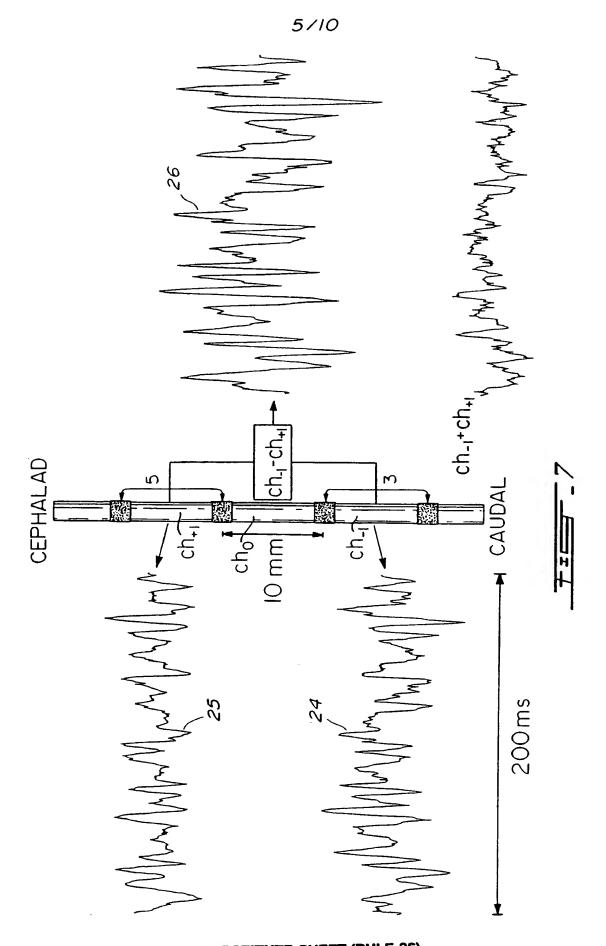


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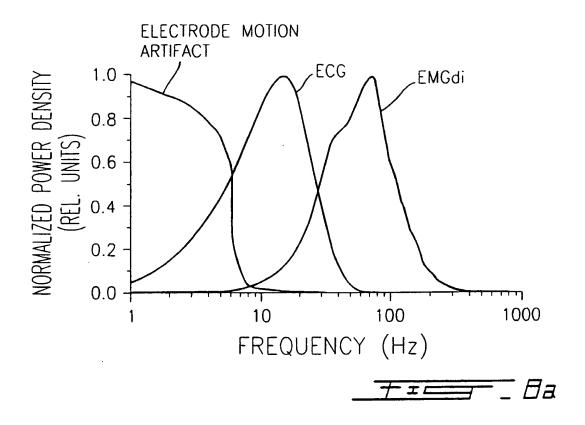


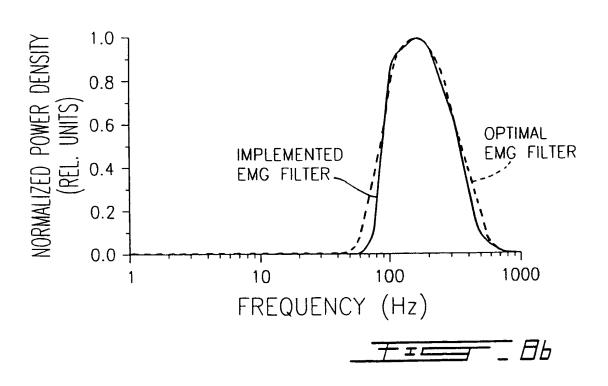
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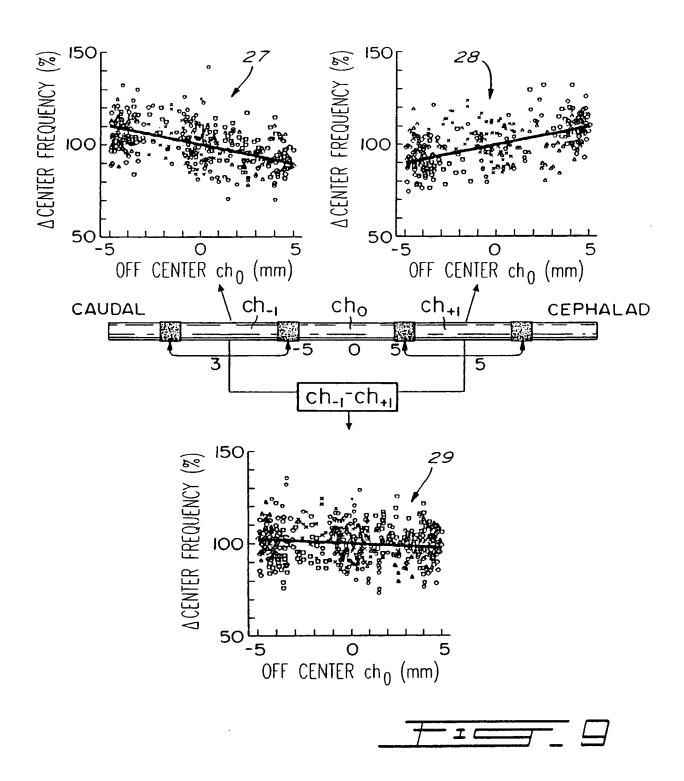


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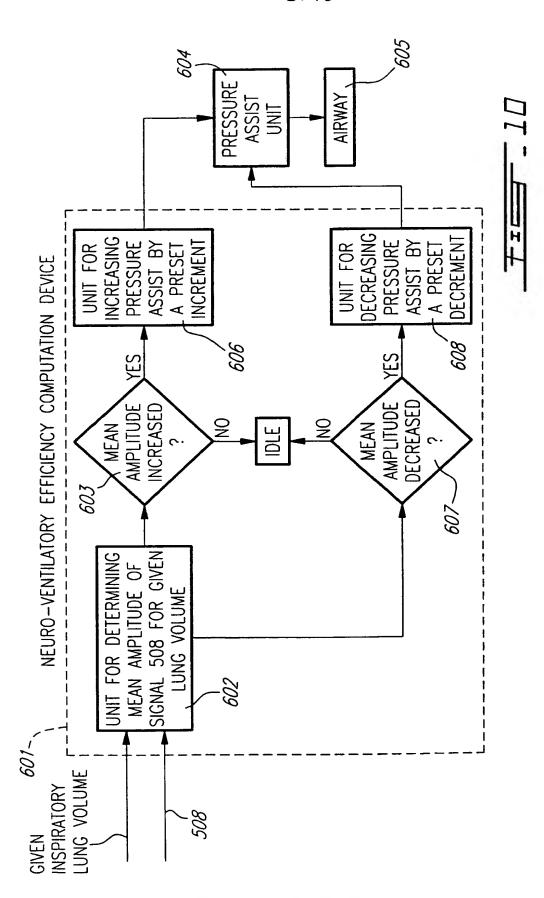




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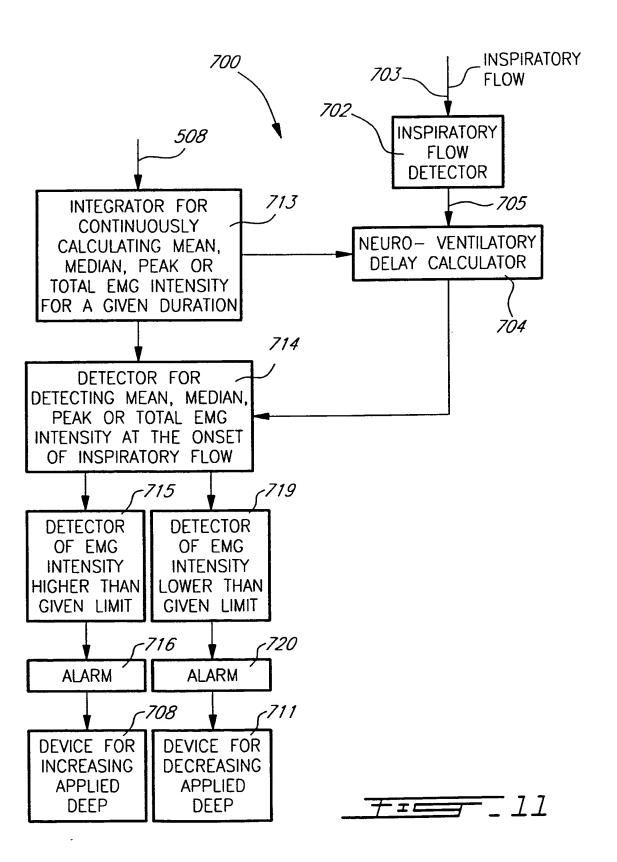


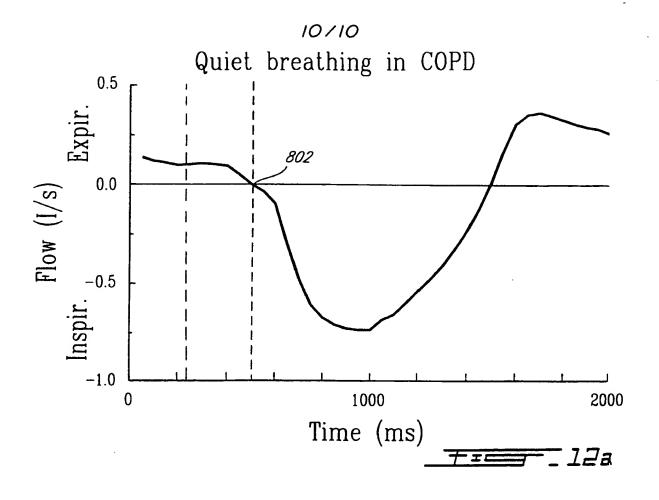
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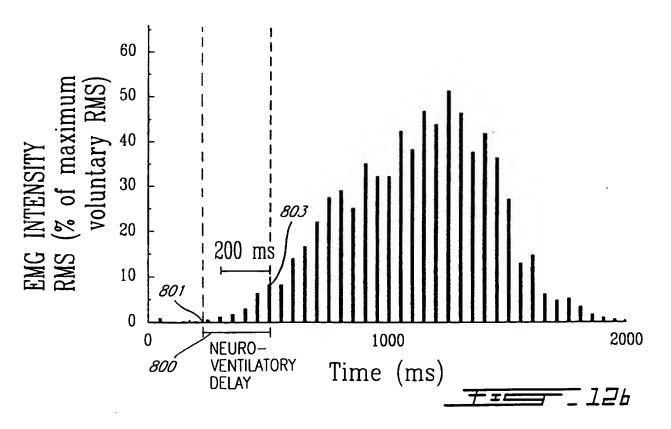


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Tional Application No

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A. CLASSIF IPC 6	FICATION OF SUBJECT MATTER A61M16/00 A61B5/0488			
According to	International Patent Classification (IPC) or to both national classificat	tion and IPC		
B. FIELDS	SEARCHED			
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Electronic da	ata base consulted during the international search (name of data bas	e and, where practical, se	earch terms used	
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT			
Category °	Citation of document, with indication, where appropriate, of the rele	vant passages		Relevant to claim No.
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	XP002115582 page 1093, left-hand column, line 22	1 - line		
Y	EP 0 776 671 A (SIEMENS ELEMA AB) 4 June 1997 (1997-06-04) column 2, line 8 - line 41			1
A	US 5 671 752 A (SINDERBY CHRISTER 30 September 1997 (1997-09-30) column 10, line 15 - line 18; fig			1
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X Furt	her documents are listed in the continuation of box C.	X Patent family me	embers are listed	in annex.
° Special ca	ent defining the general state of the art which is not	"T" later document publis or priority date and r cited to understand t	not in conflict with	the application but
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Intrational Application No
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(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference GP/10875.79		of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/CA 99/00529	04/06/1999	04/06/1998
Applicant		
UNIVERSIT DE MONTR AL et	al	
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Autansmitted to the International Bureau.	thority and is transmitted to the applicant
This International Search Report consists  X It is also accompanied by	of a total of3 sheets. a copy of each prior art document cited in this	s report.
Basis of the report     a. With regard to the language, the language in which it was filed, unl	international search was carried out on the ba ess otherwise indicated under this item.	asis of the international application in the
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2. Certain claims were fou	nd unsearchable (See Box I).	
3. Unity of invention is lack	king (see Box II).	
4. With regard to the title,		
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	hed by this Authority to read as follows: E ASSIST VENTILATION CONTRO NAL	LLED BY A DIAPHRAGM
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as suggested by the applicant fail		None of the figures.
	characterizes the invention.	



ernational Application No T/CA 99/00529 A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M16/00 A61B5/0488

According to International Patent Classification (IPC) or to both national classification and IPC

#### **B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols).

IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	E. AGOSTINI ET AL.: "Electromyography of the diaphragm in man and transdiaphragmatic pressure" JOURNAL OF APPLIED PHYSIOLOGY, vol. 15, 1960, pages 1093-1097, XP002115582 page 1093, left-hand column, line 1 - line 22	1
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Y Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  "Y" document of particular relevance; the claimed invention
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Date of the actual completion of the international search  17 September 1999	Date of mailing of the international search report $06/10/1999$
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